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SUBCHAPTER F—QUARANTINE, INSPECTION, LICENSING

PART 70—INTERSTATE QUARANTINE

Sec.

AUTHORITY: Secs. 215 and 311 of Public Health Service (PHS) Act. as amended (42 U.S.C. 216, 243); secs. 361–369, PHS Act, as amended (42 U.S.C. 264–272).

SOURCE: 65 FR 49908, Aug. 16, 2000, unless otherwise noted.

§ 70.1 General definitions.

As used in this part, terms shall have the following meaning:

(a) *Communicable diseases* means illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

(b) *Communicable period* means the period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

(c) *Conveyance* means any land or air carrier, or any vessel as defined in paragraph (h) of this section.

(d) *Incubation period* means the period between the implanting of disease organisms in a susceptible person and the appearance of clinical manifestation of the disease.

(e) *Interstate traffic* means:

(1) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State or possession—

(i) From a point of origin in any State or possession to a point of destination in any other State or possession; or

(ii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

(f) *Possession* means any of the possessions of the United States, including Puerto Rico and the Virgin Islands.

(g) *State* means any State, the District of Columbia, Puerto Rico, and the Virgin Islands.

(h) *Vessel* means any passenger-carrying, cargo, or towing vessel exclusive of:

(1) Fishing boats including those used for shell-fishing;

(2) Tugs which operate only locally in specific harbors and adjacent waters;

(3) Barges without means of self-propulsion;

(4) Construction-equipment boats and dredges; and

(5) Sand and gravel dredging and handling boats.

§ 70.2 Measures in the event of inadequate local control.

Whenever the Director of the Centers for Disease Control and Prevention determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or

articles believed to be sources of infection.

§ 70.3 All communicable diseases.

A person who has a communicable disease in the communicable period shall not travel from one State or possession to another without a permit from the health officer of the State, possession, or locality of destination, if such permit is required under the law applicable to the place of destination. Stop-overs other than those necessary for transportation connections shall be considered as places of destination.

§ 70.4 Report of disease.

The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.

§ 70.5 Certain communicable diseases; special requirements.

The following provisions are applicable with respect to any person who is in the communicable period of cholera, plague, smallpox, typhus or yellow fever, or who, having been exposed to any such disease, is in the incubation period thereof:

(a) *Requirements relating to travelers.* (1) No such person shall travel from one State or possession to another, or on a conveyance engaged in interstate traffic, without a written permit of the Surgeon General or his/her authorized representative.

(2) Application for a permit may be made directly to the Surgeon General or to his/her representative authorized to issue permits.

(3) Upon receipt of an application, the Surgeon General or his/her authorized representative shall, taking into consideration the risk of introduction, transmission, or spread of the disease from one State or possession to another, reject it, or issue a permit that may be conditioned upon compliance with such precautionary measures as he/she shall prescribe.

(4) A person to whom a permit has been issued shall retain it in his/her possession throughout the course of his/her authorized travel and comply with all conditions prescribed therein, including presentation of the permit to the operators of conveyances as required by its terms.

(b) *Requirements relating to operation of conveyances.* (1) The operator of any conveyance engaged in interstate traffic shall not knowingly:

(i) Accept for transportation any person who fails to present a permit as required by paragraph (a) of this section; or

(ii) Transport any person in violation of conditions prescribed in his/her permit.

(2) Whenever a person subject to the provisions of this section is transported on a conveyance engaged in interstate traffic, the operator thereof shall take such measures to prevent the spread of the disease, including submission of the conveyance to inspection, disinfection and the like, as an officer of the Public Health Service designated by the Surgeon General for such purposes deems reasonably necessary and directs.

§ 70.6 Apprehension and detention of persons with specific diseases.

Regulations prescribed in this part authorize the detention, isolation, quarantine, or conditional release of individuals, for the purpose of preventing the introduction, transmission, and spread of the communicable diseases listed in an Executive Order setting out a list of quarantinable communicable diseases, as provided under section 361(b) of the Public Health Service Act. Executive Order 13295, of April 4, 2003, contains the current revised list of quarantinable communicable diseases, and may be obtained at *http://www.cdc.gov,* or at *http://www.archives.gov/federal_register.* If this Order is amended, HHS will enforce that amended order immediately and update this reference.

[68 FR 17559, Apr. 10, 2003]

§70.7 Responsibility with respect to minors, wards, and patients.

A parent, guardian, physician, nurse, or other such person shall not transport, or procure or furnish transportation for any minor child or ward, patient or other such person who is in the communicable period of a communicable disease, except in accordance with provisions of this part.

§70.8 Members of military and naval forces.

The provisions of §§70.3, 70.4, 70.5, 70.7, and this section shall not apply to members of the military or naval forces, and medical care or hospital beneficiaries of the Army, Navy, Veterans' Administration, or Public Health Service, when traveling under competent orders: *Provided,* That in the case of persons otherwise subject to the provisions of §70.5 the authority authorizing the travel requires precautions to prevent the possible transmission of infection to others during the travel period.

PART 71—FOREIGN QUARANTINE

Subpart A—Definitions and General Provisions

Subpart B—Measures at Foreign Ports

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Subpart F—Importations

AUTHORITY: Secs. 215 and 311 of Public Health Service (PHS) Act. as amended (42 U.S.C. 216, 243); secs. 361–369, PHS Act, as amended (42 U.S.C. 264–272).

SOURCE: 50 FR 1519, Jan. 11, 1985, unless otherwise noted.

Subpart A—Definitions and General Provisions

§71.1 Scope and definitions.

(a) The provisions of this part contain the regulations to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the States or possessions of the United States. Regulations pertaining to preventing the interstate spread of communicable diseases are contained in 21 CFR parts 1240 and 1250.

(b) As used in this part the term:

Carrier means a ship, aircraft, train, road vehicle, or other means of transport, including military.

Communicable disease means an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person or animal or a reservoir to a susceptible host, either directly, or indirectly through an intermediate animal host, vector, or the inanimate environment.

Contamination means the presence of undesirable substances or material which may contain infectious agents or their toxic products.

Controlled Free Pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

Deratting Certificate means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, recording the inspection and deratting of the ship.

Deratting Exemption Certificate means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, recording the inspection and exemption from deratting of the ship which is rodent free.

Detention means the temporary holding of a person, ship, aircraft, or other carrier, animal, or thing in such place and for such period of time as may be determined by the Director.

Director means the Director, Centers for Disease Control, Public Health Service, Department of Health and Human Services, or his/her authorized representative.

Disinfection means the killing of infectious agents or inactivation of their toxic products outside the body by direct exposure to chemical or physical agents.

Disinfestation means any chemical or physical process serving to destroy or remove undesired small animal forms, particularly arthropods or rodents, present upon the person, the clothing, or the environment of an individual, or upon animals and carriers.

Disinsection means the operation in which measures are taken to kill the insect vectors of human disease present in carriers and containers.

Educational purpose means use in the teaching of a defined educational program at the university level or equivalent.

Exhibition purpose means use as a part of a display in a facility comparable to a zoological park or in a trained animal act. The animal display must be open to the general public at routinely scheduled hours on 5 or more days of each week. The trained animal act must be routinely scheduled for multiple performances each week and open to the general public except for reasonable vacation and retraining periods.

Ill person means a person who:

(1) Has a temperature of 100 °F. (or 38 °C.) or greater, accompanied by a rash, glandular swelling, or jaundice, or which has persisted for more than 48 hours; or

(2) Has diarrhea, defined as the occurrence in a 24-hour period of three or more loose stools or of a greater than normal (for the person) amount of loose stools.

International Health Regulations means the International Health Regulations of the World Health Organization, adopted by the Twenty-Second World Health Assembly in 1969, as amended by the Twenty-Sixth World Health Assembly in 1973, the Thirty-Fourth World Health Assembly in 1981, and as may be further amended.

International voyage means: (1) In the case of a carrier, a voyage between ports or airports of more than one country, or a voyage between ports or airports of the same country if the ship or aircraft stopped in any other country on its voyage; or (2) in the case of a person, a voyage involving entry into a country other than the country in which that person begins his/her voyage.

Isolation means: (1) When applied to a person or group of persons, the separation of that person or group of persons from other persons, except the health staff on duty, in such a manner as to prevent the spread of infection; or (2) when applied to animals, the separation of an animal or group of animals from persons, other animals, or vectors of disease in such a manner as to prevent the spread of infection.

Military services means the U.S. Army, the U.S. Air Force, the U.S. Navy, and the U.S. Coast Guard.

Scientific purpose means use for scientific research following a defined protocol and other standards for research projects as normally conducted at the university level. The term also includes the use for safety testing, potency testing, and other activities related to the production of medical products.

Surveillance means the temporary supervision of a person who may have or has been exposed to a communicable disease.

U.S. port means any seaport, airport, or border crossing point under the control of the United States.

United States means the several States, the District of Columbia,

Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

Vector means an animal (including insects) or thing which conveys or is capable of conveying infectious agents from a person or animal to another person or animal.

§ 71.2 Penalties.

Any person violating any provision of these regulations shall be subject to a fine of not more than $1,000 or to imprisonment for not more than 1 year, or both, as provided in section 368 of the Public Health Service Act (42 U.S.C. 271).

§ 71.3 Designation of yellow fever vaccination centers; Validation stamps.

(a) *Designation of yellow fever vaccination centers.* (1) The Director is responsible for the designation of yellow fever vaccination centers authorized to issue certificates of vaccination. This responsibility is delegated by the Director to a State or territorial health department with respect to yellow fever vaccination activities of non-Federal medical, public health facilities, and licensed physicians functioning within the respective jurisdictions of a State or territorial health department. Designation may be made upon application and presentation of evidence satisfactory to a State or territorial health department that the applicant has adequate facilities and professionally trained personnel for the handling, storage, and administration of a safe, potent, and pure yellow fever vaccine. Medical facilities of Federal agencies are authorized to obtain yellow fever vaccine without being designated as a yellow fever vaccination center by the Director.

(2) A designated yellow fever vaccination center shall comply with the instruction issued by the Director or by a delegated officer or employee of a State or territorial health department for the handling, storage, and administration of yellow fever vaccine. If a designated center fails to comply with such instruction, after notice to the center, the Director or, for non-Federal centers, a State or territorial health department, may revoke designation.

(b) *Validation stamps.* International Certificates of Vaccination against cholera and yellow fever issued for vaccinations performed in the United States shall be validated by:

(1) The Seal of the Public Health Service; or

(2) The Seal of the Department of State; or

(3) The stamp of the Department of Defense; or

(4) The stamp issued to the National Aeronautics and Space Administration; or

(5) The stamp issued by a State or territorial health department; or

(6) An official stamp of a design and size approved by the Director for such purpose.

Subpart B—Measures at Foreign Ports

§ 71.11 Bills of health.

A carrier at any foreign port clearing or departing for any U.S. port shall not be required to obtain or deliver a bill of health.

Subpart C—Notice of Communicable Disease Prior to Arrival

§ 71.21 Radio report of death or illness.

(a) The master of a ship destined for a U.S. port shall report immediately to the quarantine station at or nearest the port at which the ship will arrive, the occurrence, on board, of any death or any ill person among passengers or crew (including those who have disembarked or have been removed) during the 15-day period preceding the date of expected arrival or during the period since departure from a U.S. port (whichever period of time is shorter).

(b) The commander of an aircraft destined for a U.S. airport shall report immediately to the quarantine station at or nearest the airport at which the aircraft will arrive, the occurrence, on board, of any death or ill person among passengers or crew.

(c) In addition to paragraph (a) of this section, the master of a ship carrying 13 or more passengers must report by radio 24 hours before arrival the number of cases (including zero) of diarrhea in passengers and crew recorded in the ship's medical log during the current cruise. All cases of diarrhea that occur after the 24 hour report must also be reported not less than 4 hours before arrival.

(Approved by the Office of Management and Budget under control number 0920–0134)

Subpart D—Health Measures at U.S. Ports: Communicable Diseases

§ 71.31 General provisions.

(a) Upon arrival at a U.S. port, a carrier will not undergo inspection unless the Director determines that a failure to inspect will present a threat of introduction of communicable diseases into the United States, as may exist when the carrier has on board individual(s) reportable in accordance with § 71.21 or meets the circumstances described in § 71.42. Carriers not subject to inspection under this section will be subject to sanitary inspection under § 71.41 of this part.

(b) The Director may require detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease. The Director may issue a controlled free pratique to the carrier stipulating what measures are to be met, but such issuance does not prevent the periodic boarding of a carrier and the inspection of persons and records to verify that the conditions have been met for granting the pratique.

§ 71.32 Persons, carriers, and things.

(a) Whenever the Director has reason to believe that any arriving person is infected with or has been exposed to any of the communicable diseases listed in an Executive Order, as provided under section 361(b) of the Public Health Service Act, he/she may isolate, quarantine, or place the person under surveillance and may order disinfection or disinfestation, fumigation, as he/she considers necessary to prevent the introduction, transmission or spread of the listed communicable diseases. Executive Order 13295, of April 4, 2003, contains the current revised list of quarantinable communicable diseases, and may be obtained at *http://www.cdc.gov* and *http://www.archives.gov/federal_register.* If this Order is amended, HHS will enforce that amended order immediately and update this reference.

(b) Whenever the Director has reason to believe that any arriving carrier or article or thing on board the carrier is or may be infected or contaminated with a communicable disease, he/she may require detention, disinfection, disinfestation, fumigation, or other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases.

[68 FR 17559, Apr. 10, 2003]

§ 71.33 Persons: Isolation and surveillance.

(a) Persons held in isolation under this subpart may be held in facilities suitable for isolation and treatment.

(b) The Director may require isolation where surveillance is authorized in this subpart whenever the Director considers the risk of transmission of infection to be exceptionally serious.

(c) Every person who is placed under surveillance by authority of this subpart shall, during the period of surveillance:

(1) Give information relative to his/her health and his/her intended destination and report, in person or by telephone, to the local health officer having jurisdiction over the areas to be visited, and report for medical examinations as may be required;

(2) Upon arrival at any address other than that stated as the intended destination when placed under surveillance, or prior to departure from the United States, inform, in person or by telephone, the health officer serving the health jurisdiction from which he/she is departing.

(d) From time to time the Director may, in accordance with section 322 of the Public Health Service Act, enter into agreements with public or private

medical or hospital facilities for providing care and treatment for persons detained under this part.

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[50 FR 1519, Jan. 11, 1985; 50 FR 3910, Jan. 29, 1985]

§ 71.34 Carriers of U.S. military services.

(a) Carriers belonging to or operated by the military services of the United States may be exempted from inspection if the Director is satisfied that they have complied with regulations of the military services which also meet the requirements of the regulations in this part. (For applicable regulations of the military services, see Army Regulation No. 40–12, Air Force Regulation No. 161–4, Secretary of the Navy Instruction 6210.2, and Coast Guard Commandant Instruction 6210.2).

(b) Notwithstanding exemption from inspection of carriers under this section, animals or articles on board shall be required to comply with the applicable requirements of subpart F of this part.

§ 71.35 Report of death or illness on carrier during stay in port.

The master of any carrier at a U.S. port shall report immediately to the quarantine station at or nearest the port the occurrence, on board, of any death or any ill person among passengers or crew.

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Subpart E—Requirements Upon Arrival at U.S. Ports: Sanitary Inspection

§ 71.41 General provisions.

Carriers arriving at a U.S. port from a foreign area shall be subject to a sanitary inspection to determine whether there exists rodent, insect, or other vermin infestation, contaminated food or water, or other insanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable disease.

§ 71.42 Disinfection of imports.

When the cargo manifest of a carrier lists articles which may require disinfection under the provisions of this part, the Director shall disinfect them on board or request the appropriate customs officer to keep the articles separated from the other cargo pending appropriate disposition.

§ 71.43 Exemption for mails.

Except to the extent that mail contains any article or thing subject to restrictions under subpart F of this part, nothing in the regulations in this part shall render liable to detention, disinfection, or destruction any mail conveyed under the authority of the postal administration of the United States or of any other Government.

§ 71.44 Disinsection of aircraft.

(a) The Director may require disinsection of an aircraft if it has left a foreign area that is infected with insect-borne communicable disease and the aircraft is suspected of harboring insects of public health importance.

(b) Disinsection shall be the responsibility of the air carrier or, in the case of aircraft not for hire, the pilot in command, and shall be subject to monitoring by the Director.

(c) Disinsection of the aircraft shall be accomplished immediately after landing and blocking.

(1) The cargo compartment shall be disinsected before the mail, baggage, and other cargo are discharged.

(2) The rest of the aircraft shall be disinsected after passengers and crew deplane.

(d) Disinsection shall be performed with an approved insecticide in accordance with the manufacturer's instructions. The current list of approved insecticides and sources may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, GA 30333.

§ 71.45 Food, potable water, and waste: U.S. seaports and airports.

(a) Every seaport and airport shall be provided with a supply of potable water from a watering point approved by the Commissioner of Food and Drugs, Food and Drug Administration, in accordance with standards established in title

21, Code of Federal Regulations, parts 1240 and 1250.

(b) All food and potable water taken on board a ship or aircraft at any seaport or airport intended for human consumption thereon shall be obtained from sources approved in accordance with regulations cited in paragraph (a) of this section.

(c) Aircraft inbound or outbound on an international voyage shall not discharge over the United States any excrement, or waste water or other polluting materials. Arriving aircraft shall discharge such matter only at servicing areas approved under regulations cited in paragraph (a) of this section.

§ 71.46 Issuance of Deratting Certificates and Deratting Exemption Certificates.

Valid Deratting Certificates or Deratting Exemption Certificates are not required for ships to enter a U.S. seaport. In accordance with Article 17 of the International Health Regulations, the Public Health Service may perform rodent infestation inspections and issue Deratting Certificates and Deratting Exemption Certificates.

§ 71.47 Special provisions relating to airports: Office and isolation facilities.

Each U.S. airport which receives international traffic shall provide without cost to the Government suitable office, isolation, and other exclusive space for carrying out the Federal responsibilities under this part.

§ 71.48 Carriers in intercoastal and interstate traffic.

Carriers, on an international voyage, which are in traffic between U.S. ports, shall be subject to inspection as described in §§ 71.31 and 71.41 when there occurs on board, among passengers or crew, any death, or any ill person, or when illness is suspected to be caused by insanitary conditions.

Subpart F—Importations

§ 71.51 Dogs and cats.

(a) *Definitions.*

As used in this section the term:

Cat means all domestic cats.

Confinement means restriction of a dog or cat to a building or other enclosure at a U.S. port, en route to destination and at destination, in isolation from other animals and from persons except for contact necessary for its care or, if the dog or cat is allowed out of the enclosure, muzzling and keeping it on a leash.

Dog means all domestic dogs.

Owner means owner or agent.

Valid rabies vaccination certificate means a certificate which was issued for a dog not less than 3 months of age at the time of vaccination and which:

(1) Identifies a dog on the basis of breed, sex, age, color, markings, and other identifying information.

(2) Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog at a U.S. port.

(3) Specifies a date of expiration which is after the date of arrival of the dog at a U.S. port. If no date of expiration is specified, then the date of vaccination shall be no more than 12 months before the date of arrival at a U.S. port.

(4) Bears the signature of a licensed veterinarian.

(b) *General requirements for admission of dogs and cats*—(1) *Inspection by Director.* The Director shall inspect all dogs and cats which arrive at a U.S. port, and admit only those dogs and cats which show no signs of communicable disease as defined in § 71.1.

(2) *Examination by veterinarian and confinement of dogs and cats.* When, upon inspection, a dog or cat does not appear to be in good health on arrival (e.g., it has symptoms such as emaciation, lesions of the skin, nervous system disturbances, jaundice, or diarrhea), the Director may require prompt confinement and give the owner an opportunity to arrange for a licensed veterinarian to examine the animal and give or arrange for any tests or treatment indicated. The Director will consider the findings of the examination and tests in determining whether or not the dog or cat may have a communicable disease. The owner shall bear the expense of the examination, tests, and treatment. When it is necessary to detain a dog or cat pending determination of its admissibility, the owner shall provide confinement facilities

which in the judgment of the Director will afford protection against any communicable disease. The owner shall bear the expense of confinement. Confinement shall be subject to conditions specified by the Director to protect the public health.

(3) *Record of sickness or death of dogs and cats and requirements for exposed animals.* (i) The carrier responsible for the care of dogs and cats shall maintain a record of sickness or death of animals en route to the United States and shall submit the record to the quarantine station at the U.S. port upon arrival. Dogs or cats which have become sick while en route or are dead on arrival shall be separated from other animals as soon as the sickness or death is discovered, and shall be held in confinement pending any necessary examination as determined by the Director.

(ii) When, upon inspection, a dog or cat appears healthy but, during shipment, has been exposed to a sick or dead animal suspected of having a communicable disease, the exposed dog or cat shall be admitted only if examination or tests made on arrival reveal no evidence that the animal may be infected with a communicable disease. The provisions of paragraph (b)(2) of this section shall be applicable to the examination or tests.

(4) *Sanitation.* When the Director finds that the cages or other containers of dogs or cats arriving in the United States are in an insanitary or other condition that may constitute a communicable disease hazard, the dogs or cats shall not be admitted in such containers unless the owner has the containers cleaned and disinfected.

(c) *Rabies vaccination requirements for dogs.* (1) A valid rabies vaccination certificate is required at a U.S. port for admission of a dog unless the owner submits evidence satisfactory to the Director that:

(i) If a dog is less than 6 months of age, it has been only in a country determined by the Director to be rabies-free (a current list of rabies-free countries may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, GA 30333); or

(ii) If a dog is 6 months of age or older, for the 6 months before arrival, it has been only in a country determined by the Director to be rabies-free; or

(iii) The dog is to be taken to a research facility to be used for research purposes and vaccination would interfere with its use for such purposes.

(2) Regardless of the provisions of paragraph (c)(1) of this section, the Director may authorize admission as follows:

(i) If the date of vaccination shown on the vaccination certificate is less than 30 days before the date of arrival, the dog may be admitted, but must be confined until at least 30 days have elapsed since the date of vaccination;

(ii) If the dog is less than 3 months of age, it may be admitted, but must be confined until vaccinated against rabies at 3 months of age and for at least 30 days after the date of vaccination;

(iii) If the dog is 3 months of age or older, it may be admitted, but must be confined until it is vaccinated against rabies. The dog must be vaccinated within 4 days after arrival at destination but no more than 10 days after arrival at a U.S. port. It must be kept in confinement for at least 30 days after the date of vaccination.

(3) When a dog is admitted under paragraph (c)(2) of this section, the Director shall notify the health department or other appropriate agency having jurisdiction at the point of destination and shall provide the address of the specified place of confinement and other pertinent information to facilitate surveillance and other appropriate action.

(d) *Certification requirements.* The owner shall submit such certification regarding confinement and vaccination prescribed under this section as may be required by the Director.

(e) *Additional requirements for the importation of dogs and cats.* Dogs and cats shall be subject to such additional requirements as may be deemed necessary by the Director or to exclusion if coming from areas which the Director has determined to have high rates of rabies.

(f) *Requirements for dogs and cats in transit.* The provisions of this section

shall apply to dogs and cats transported through the United States from one foreign country to another, except as provided below:

(1) Dogs and cats that appear healthy, but have been exposed to a sick or dead animal suspected of having a communicable disease, need not undergo examination or tests as provided in paragraph (b)(3) of this section if the Director determines that the conditions under which they are being transported will afford adequate protection against introduction of communicable disease.

(2) Rabies vaccination is not required for dogs that are transported by aircraft or ship and retained in custody of the carrier under conditions that would prevent transmission of rabies.

(g) *Disposal of excluded dogs and cats.* A dog or cat excluded from the United States under the regulations in this part shall be exported or destroyed. Pending exportation, it shall be detained at the owner's expense in the custody of the U.S. Customs Service at the U.S. port.

(Approved by the Office of Management and Budget under control number 0920–0134)

§ 71.52 Turtles, tortoises, and terrapins.

(a) *Definitions.*

As used in this section the term:

Turtles includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order *Testudinata,* class *Reptilia,* except marine species (Families *Dermochelidae* and *Cheloniidae*).

(b) *Importation; general prohibition.* Except as otherwise provided in this section, live turtles with a carapace length of less than 4 inches and viable turtle eggs may not be imported into the United States.

(c) *Exceptions.* (1) Live turtles with a carapace length of less than 4 inches and viable turtle eggs may be imported into the United States, provided that such importation is not in connection with a business, and the importation is limited to lots of fewer than seven live turtles or fewer than seven viable turtle eggs, or any combinations of such turtles and turtle eggs totaling fewer than seven, for any entry.

(2) Seven or more live turtles with a carapace length of less than 4 inches, or seven or more viable turtle eggs or any combination of turtles and turtle eggs totaling seven or more, may be imported into the United States for bona fide scientific or educational purposes or for exhibition when accompanied by a permit issued by the Director.

(3) The requirements in paragraphs (c)(1) and (c)(2) of this section shall not apply to the eggs of marine turtles excluded from these regulations under § 71.52(a).

(d) *Application for permits.* Applications for permits to import turtles, as set forth in paragraph (c)(2) of this section, shall be made by letter to the Director, and shall contain, identify, or describe, the name and address of the applicant, the number of specimens, and the common and scientific names of each species to be imported, the holding facilities, the intended use of the turtles following their importation, the precautions to be undertaken to prevent infection of members of the public with *Salmonella* and *Arizona* bacteria, and any other information and assurances the Director may require.

(e) *Criteria for issuance of permits.* A permit may be issued upon a determination that the holder of the permit will isolate or otherwise confine the turtles and will take such other precautions as may be determined by the Director to be necessary to prevent infection of members of the public with *Salmonella* and *Arizona* bacteria and on condition that the holder of the permit will provide such reports as the Director may require.

(f) *Interstate Regulations.* Upon admission at a U.S. Port, turtles and viable turtle eggs become subject to Food and Drug Administration Regulations (21 CFR 1240.62) regarding general prohibition.

(g) *Other permits.* Permits to import certain species of turtles may be required under other Federal regulations (50 CFR parts 17 and 23) protecting such species.

(Approved by the Office of Management and Budget under control number 0920–0134)

§ 71.53 Nonhuman primates.

(a) *Definitions.*

As used in this section the term:

Importer means any person or corporation, partnership, or other organization, receiving live nonhuman primates from a foreign country within a period of 31 days, beginning with the importation date, whether or not the primates were held for part of the period at another location. The term *importer* includes the original importer and any other person or organization receiving imported primates within the 31-day period.

Nonhuman primates means all nonhuman members of the Order Primates, including, but not limited to, animals commonly known as monkeys, chimpanzees, orangutans, gorillas, gibbons, apes, baboons, marmosets, tamarin, lemurs, and lorises.

(b) *General prohibition.* No person or organization may import live nonhuman primates into the United States unless registered as an importer in accordance with applicable provisions of this section.

(c) *Uses for which nonhuman primates may be imported and distributed.* Live nonhuman primates may be imported into the United States and sold, resold, or otherwise distributed only for bona fide scientific, educational, or exhibition purposes. The importation of nonhuman primates for use in breeding colonies is also permitted provided that all offspring will be used only for scientific, educational, or exhibition purposes. The maintenance of nonhuman primates as pets, hobby, or an avocation with occasional display to the general public is not a permissible use.

(d) *Registration of importers.* (1) Importers of nonhuman primates shall register with the Director in a manner prescribed by the Director.

(2) Documentary evidence that an importer will use all nonhuman primates solely for the permitted purposes is required.

(3) Registration shall inlcude certification that the nonhuman primates will not be shipped, sold, or otherwise transferred to other persons or organizations without adequate proof that the primates will be used only for the permitted purposes.

(4) Registration shall be for 2 years, effective the date the application for registration is approved by the Director.

(5) Registration may be renewed by filing a registration application form with the Director not less than 30 days nor more than 60 days before expiration of the current registration.

(e) *Recordkeeping and reporting requirement for registered importers.* (1) Importers shall maintain records on each shipment of imported nonhuman primates received. The record on each shipment shall include the number of primates received, species, country of origin, date of importation, the number of primates in the shipment that die within 90 days after receipt, and cause(s) of deaths. If any primates in the shipment are sold or otherwise distributed within 90 days after receipt, the record shall include the number of primates in each shipment or sale, the dates of each shipment or sale, and the identity of the recipients. In addition, the record shall contain copies of documents that were presented to the importer to establish that the recipient would use the primates solely for the permitted purposes. The records shall be maintained in an organized manner in a central location at or in close proximity to the importer's primate holding facility. The records shall be maintained for a period of 3 years and shall be available for inspection by the Director at any time.

(2) Importers shall report to the Director by telephone within 24 hours the occurrence of any illness in nonhuman primates that is suspected of being yellow fever, monkeypox, or Marburg/Ebola disease.

(3) Importers also shall report to the Director by telephone within 24 hours the occurrence of illness in any member of their staff suspected of having an infectious disease acquired from nonhuman primates.

(f) *Disease control measures.* Upon receipt of evidence of exposure of nonhuman primates to a communicable disease that may constitute a threat to public health, the Director may provide for or require examination, treatment, detention, isolation, seizure, or destruction of exposed animals. Any measures required shall be at the owner's expense.

(g) *Disposal of excluded nonhuman primates.* Nonhuman primate(s) excluded from the United States by provisions of this section shall, at the owner's option and expense, be exported, destroyed, or given to a scientific, educational, or exhibition facility under arrangements approved by the Director. If the owner fails to dispose of the nonhuman primate by one of the approved options or fails to select a method of disposal within 7 days, the Director will select the method of disposal. Pending disposal, the nonhuman primate(s) shall be detained at the owner's expense in custody of the U.S. Customs Service at the U.S. port.

(h) *Revocation of an importer's registration.* (1) An importer's registration may be revoked by the Director, upon notice to the importer holding such registration, if the Director determines that the importer has failed to comply with any applicable provisions of this section. The notice shall contain a statement of the grounds upon which the revocation is based.

(2) The importer may file an answer within 20 days after receipt of the notice. Answers shall admit or deny specifically, and in detail, each allegation in the notice. Allegations in the notice not denied by answer shall be deemed admitted. Matters alleged as affirmative defenses shall be separately stated and numbered. Failure of the importer to file an answer within 20 days after receipt of the notice may be deemed an admission of all allegations of fact recited in the notice.

(3) The importer shall be entitled to a hearing with respect to the revocation upon filing a written request, either in the answer or in a separate document, with the Director within 20 days after the effective date of revocation. Failure to request a hearing shall be deemed a waiver of hearing and as consent to the submission of the case to the Director for decision based on the written record. The failure both to file an answer and to request a hearing shall be deemed to constitute consent to the making of a decision on the basis of available information.

(4) As soon as practicable after the completion of any hearing conducted pursuant to the provisions of this section, the Director shall render a final decision. A copy of such decision shall be served on the importer.

(5) An importer's registration which has been revoked may be reinstated by the Director upon inspection, examination of records, conference with the importer, and receipt of information and assurances of compliance with the requirements of this section.

(i) *Other permits.* In addition to the requirements under this section, permits to import certain species of nonhuman primates may also be required under other Federal regulations (50 CFR parts 17 and 23) protecting such species.

(Approved by the Office of Management and Budget under control number 0920–0134)

§ 71.54 Etiological agents, hosts, and vectors.

(a) A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

(b) Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

§ 71.55 Dead bodies.

The remains of a person who died of a communicable disease listed in §71.32(b) may not be brought into a U.S. port unless the body is (a) properly embalmed and placed in a hermetically sealed casket, (b) cremated, or (c) accompanied by a permit issued by the Director.

§ 71.56 African rodents and other animals that may carry the monkeypox virus.

(a) *What actions are prohibited*? *What animals are affected*? (1) Except as provided in paragraphs (a)(2) and (a)(3) of this section,

(i) You must not import or attempt to import any rodents, whether dead or alive, that were obtained, directly or

indirectly, from Africa, or whose native habitat is Africa, any products derived from such rodents, any other animal, whether dead or alive, whose importation the Director has prohibited by order, or any products derived from such animals; and

(ii) You must not prevent or attempt to prevent the Centers for Disease Control and Prevention (CDC) from causing an animal to be quarantined, re-exported, or destroyed under a written order.

(2) The prohibitions in paragraph (a)(1) of this section do not apply if you have written permission from CDC to import a rodent that was obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or an animal whose importation the Director has prohibited by order.

(i) To obtain such written permission from CDC, you must send a written request to Division of Global Migration and Quarantine, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333. You may also fax your request to the Division of Global Migration and Quarantine (using the same address in the previous sentence) at 404–498–1633.

(ii) Your request must state the reasons why you need an exemption, describe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an exemption will not result in the spread of monkeypox within the United States. Your request must be limited to scientific, exhibition, or educational purposes.

(iii) We will respond in writing to all requests, and we also may impose conditions in granting an exemption. If we deny your request, you may appeal that denial. Your appeal must be in writing and be submitted to the CDC official whose office denied your request, and you must submit the appeal within two business days after you receive the denial. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

(3) The prohibitions in paragraph (a) of this section do not apply to products derived from rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or products derived from any other animal whose importation the Director has prohibited by order if such products have been properly processed to render them noninfectious so that they pose no risk of transmitting or carrying the monkeypox virus. Such products include, but are not limited to, fully taxidermied animals and completely finished trophies; and they may be imported without written permission from CDC.

(b) *What actions can CDC take*? (1) To prevent the monkeypox virus from spreading and becoming established in the United States, we may, in addition to any other authorities under this part:

(i) Issue an order causing an animal to be placed in quarantine,

(ii) Issue an order causing an animal to be re-exported,

(iii) Issue an order causing an animal to be destroyed, or

(iv) Take any other action necessary to prevent the spread of the monkeypox virus.

(2) Any order causing an animal to be quarantined, re-exported, or destroyed will be in writing.

(c) *How do I appeal an order*? If you received a written order to quarantine or re-export an animal or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and be submitted to the CDC official whose office issued the order, and you must submit the appeal within 2 business days after you receive the order. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written

response to the appeal, which shall constitute final agency action.

[68 FR 62369, Nov. 4, 2003]

PART 72—INTERSTATE SHIPMENT OF ETIOLOGIC AGENTS [1]

Sec.

AUTHORITY: 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; 42 U.S.C. 262 note.

SOURCE: 45 FR 48627, July 21, 1980, unless otherwise noted.

§ 72.1 Definitions.

As used in this part:

Biological product means a biological product prepared and manufactured in accordance with the provisions of 9 CFR parts 102–104 and 21 CFR parts 312 and 600–680 and which, in accordance with such provisions, may be shipped in interstate traffic.

Diagnostic specimen means any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

Etiologic agent means a viable microorganism or its toxin which causes, or may cause, human disease.

Interstate traffic means the movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession, (a) from a point of origin in any State or possession to a point of destination in any other State or possession, or (b) between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

§ 72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.

No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material including, but not limited to, diagnostic specimens and biological products which such person reasonably believes may contain an etiologic agent unless such material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

§ 72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.

Notwithstanding the provisions of § 72.2, no person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material (other than biological products) known to contain, or reasonably believed by such person to contain, one or more of the following etiologic agents unless such material is packaged, labeled, and shipped in accordance with the requirements specified in paragraphs (a) through (f) of this section:

BACTERIAL AGENTS

Acinetobacter calcoaceticus.
Actinobacillus— all species.
Actinomycetaceae— all members.
Aeromonas hydrophila.
Arachnia propionica.
Arizona hinshawii— all serotypes.
Bacillus anthracis.
Bacteroides spp.
Bartonella— all species.
Bordetella— all species.
Borrelia recurrentis, B. vincenti.
Brucella— all species.
Campylobacter (Vibrio) foetus, C. (Vibrio) jejuni.
Chlamydia psittaci, C. trachomatis.
Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum,Cl. novyi, Cl. septicum, Cl. tetani.

[1] The requirements of this part are in addition to and not in lieu of any other packaging or other requirements for the transportation of etiologic agents in interstate traffic prescribed by the Department of Transportation and other agencies of the Federal Government.

Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale.
Edwarsiella tarda.
Erysipelothrix insidiosa.
Escherichia coli, all enteropathogenic serotypes.
Francisella (Pasteurella) Tularensis.
Haemophilus ducreyi, H. influenzae.
Klebsiella— all species and all serotypes.
Legionella— all species and all Legionella-like organisms.
Leptospira interrogans— all serovars.
Listeria— all species.
Mimae polymorpha.
Moraxella— all species.
Mycobacterium— all species.
Mycoplasma— all species.
Neisseria gonorrhoeae, N. meningitidis.
Nocardia asteroides.
Pasteurella— all species.
Plesiomonas shigelloides.
Proteus— all species.
Pseudomonas mallei.
Pseudomonas pseudomallei.
Salmonella— all species and all serotypes.
Shigella— all species and all serotypes.
Sphaerophorus necrophorus.
Staphylococcus aureus.
Streptobacillus moniliformis.
Streptococcus pneumoniae.
Streptococcus pyogenes.
Treponema careteum, T. pallidum, and *T. pertenue.*
Vibrio cholerae, V. parahemolyticus.
Yersinia (Pasteurella) pestis, Y. enterocolitica.

FUNGAL AGENTS

Blastomyces dermatitidis.
Coccidioides immitis.
Cryptococcus neoformans.
Histoplasma capsulatum.
Paracoccidioides brasiliensis.

VIRAL AND RICKETTSIAL AGENTS

Adenoviruses—human—all types.
Arboviruses—all types.
Coxiella burnetii.
Coxsackie A and B viruses—all types.
Creutzfeldt—Jacob agent
Cytomegaloviruses.
Dengue viruses—all types.
Ebola virus.
Echoviruses—all types.
Encephalomyocarditis virus.
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
Hepatitis associated materials (hepatitis A, hepatitis B, hepatitis nonA-nonB).
Herpesvirus—all members.
Infectious bronchitis-like virus.
Influenza viruses—all types.
Kuru agent.
Lassa virus.
Lymphocytic choriomeningitis virus.
Marburg virus.
Measles virus.
Mumps virus.
Parainfluenza viruses—all types.
Polioviruses—all types.
Poxviruses—all members.
Rabies virus—all strains.
Reoviruses—all types.
Respiratory syncytial virus.
Rhinoviruses—all types.
Rickettsia— all species.
Rochalimaea quintana.
Rotaviruses—all types.
Rubella virus.
Simian virus 40.
Tick-borne encephalitis virus complex, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.
Vaccinia virus.
Varicella virus.
Variola major and Variola minor viruses.
Vesicular stomatis viruses—all types.
White pox viruses.
Yellow fever virus.[2]

(a) *Volume not exceeding 50 ml.* Material shall be placed in a securely closed, watertight container (primary container (test tube, vial, etc.)) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

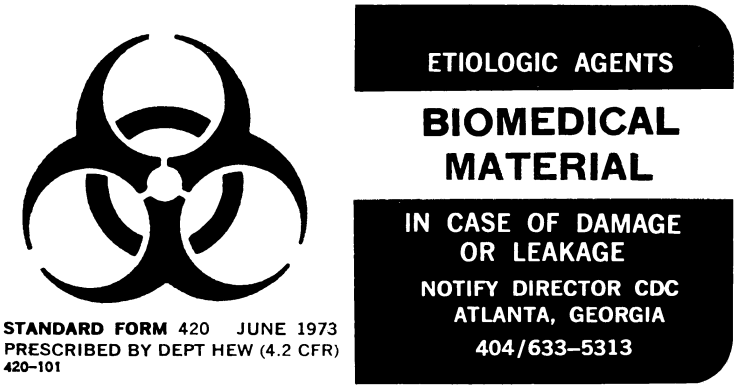
(b) *Volume greater than 50 ml.* Packaging of material in volumes of 50 ml. or more shall comply with requirements specified in paragraph (a) of this section. In addition, a shock absorbent material, in volume at least equal to

[2] This list may be revised from time to time by Notice published in the FEDERAL REGISTER to identify additional agents which must be packaged in accordance with the requirements contained in this part.

that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml may be placed in a single, secondary container. The maximum amount of etiologic agent which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

(c) *Dry ice.* If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbent material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(d)(1) The outer shipping container of all materials containing etiologic agents transported in interstate traffic must bear a label as illustrated and described below:



(2) The color of material on which the label is printed must be white, the symbol red, and the printing in red or white as illustrated.

(3) The label must be a rectangle measuring 51 millimeters (mm) (2 inches) high by 102.5 mm (4 inches) long.

(4) The red symbol measuring 38 mm (1½ inches) in diameter must be centered in a white square measuring 51 mm (2 inches) on each side.

(5) Type size of the letters of label shall be as follows:

Etiologic agents—10 pt. rev.
Biomedical material—14 pt.
In case of damage or leakage—10 pt. rev.
Notify Director CDC, Atlanta, Georgia—8 pt. rev.
404–633–5313—10 pt. rev.

(e) *Damaged packages.* The carrier shall promptly, upon discovery of evidence of leakage or any other damage to packages bearing an Etiologic Agents/Biomedical Material label, isolate the package and notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333, by telephone: (404) 633–5313. The carrier shall also notify the sender.

(f) *Registered mail or equivalent system.* Transportation of the following etiologic agents shall be by registered mail or an equivalent system which requires or provides for sending notification of receipt to the sender immediately upon delivery:

Coccidioides immitis.
Ebola virus.
Francisella (Pasteurella) tularensis.
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.

Herpesvirus simiae (B virus).
Histoplasma capsulatum.
Lassa virus.
Marburg virus.
Pseudomonas mallei.
Pseudomonas pseudomallei.
Tick-borne encephalitis virus complex including, but not limited to, Russian spring-summer encephalitis, Kyasanur forest disease, Omsk Hemorrhagic fever, and Central European encephalitis viruses, Variola minor, and Variola major.
Variola major, Variola minor, and Whitepox viruses.
Yersinia (Pasteurella) pestis.[3]

§ 72.4 Notice of delivery; failure to receive.

When notice of delivery of materials known to contain or reasonably believed to contain etiologic agents listed in § 72.3(f) is not received by the sender within 5 days following anticipated delivery of the package, the sender shall notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333 (telephone (404) 633–5313).

§ 72.5 Requirements; variations.

The Director, Center for Disease Control, may approve variations from the requirements of this section if, upon review and evaluation, it is found that such variations provide protection at least equivalent to that provided by compliance with the requirements specified in this section and such findings are made a matter of official record.

§ 72.6 Additional requirements for facilities transferring or receiving select agents.

(a) *Registration of facilities.* (1) Prior to transferring or receiving a select agent listed in Appendix A of this part, a facility shall register with a registering entity authorized by the Secretary (paragraph (c) of this section) or be approved by the Secretary as equipped and capable of handling the covered agent at Biosafety Level (BL) 2, 3, or 4, depending on the agent.

(2) Registration will include:

(i) Sufficient information provided by the responsible facility official indicating that the applicant facility, and its laboratory or laboratories, are equipped and capable of handling the agents at BL 2, 3, or 4, depending upon the agent, and the type of work being performed with the agents;

(ii) Inspection of the applicant facility at the discretion of the Secretary or the registering entity in consultation with the Secretary;

(iii) Issuance by the registering entity of a registration number unique to each facility;

(iv) Collection of a periodic site registration fee by the registering entity or the Secretary.

A schedule of fees collected by the Secretary to cover the direct costs (e.g., salaries, equipment, travel) and indirect costs (e.g., rent, telephone service and a proportionate share of management and administration costs) related to administration of this part will be published in the FEDERAL REGISTER and updated annually.

(v) Follow-up inspections of the facility by the registering entity or the Secretary, as appropriate, to ensure the facility continues to meet approved standards and recordkeeping requirements.

(3) Such registration shall remain effective until relinquished by the facility or withdrawn by the Secretary or the registering entity.

(4) The registration may be denied or withdrawn by the registering entity or the Secretary based on:

(i) Evidence that the facility is not or is no longer capable of handling covered agents at the applicable biosafety level;

(ii) Evidence that the facility has handled covered agents in a manner in contravention of the applicable biosafety level requirements;

(iii) Evidence that the facility has or intends to use covered agents in a manner harmful to the health of humans;

(iv) Evidence that the facility has failed to comply with any provisions of this part or has acted in a manner in contravention of this part; or

(v) Failure to pay any required registration fee.

[3] This list may be revised from time to time by Notice published in the FEDERAL REGISTER to identify additional agents which must be transported in accordance with requirements contained in § 72.3(f).

(5) The biosafety standards and requirements for BSL–2, 3, and 4 operations are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Fourth Edition, May 1999 which is hereby incorporated by reference. The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR part 51 the incorporation by reference of the above publication. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop A–13 Atlanta, Georgia, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* The manual is also available on the CDC web site at *www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm.*

(6) Additional specific requirements for handling toxins subject to this part must be met and are found in 29 CFR §1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories."

(b) *Appeals.* A decision made by the Secretary or a registering entity to deny or withdraw registration of a particular facility may be appealed to the Secretary. An application for appeal must be received by the Secretary no later than 14 days after the appealing party's application for registration was denied or no later than 14 days after the appealing party's registration was withdrawn. The application must clearly identify the issues presented by the appeal and fully explain the appealing party's position with respect to those issues. The Secretary may allow the filing of opposing briefs, informal conferences, or whatever steps the Secretary considers appropriate to fairly resolve the appeal.

(c) *Authorized registering entities.* (1) the Secretary may authorize a state agency or private entity to register facilities under paragraph (a) of this section, if the Secretary determines that the registering entity's criteria for determining the biosafety standards for facilities handling select agents are consistent with the requirements contained in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories," Fourth Edition.

(2) A registering entity shall maintain:

(i) A database of all facilities formerly and currently registered as BL 2, 3, or 4 and capable of working with agents in Appendix A of this part. The database shall include the name and address of the registered facility, the date the facility was registered, the facility's registration number, and the name and phone number of the responsible facility official.

(ii) A copy of each CDC Form EA–101 transmitted by each transferor registered by that registering entity. Such forms shall be made readily accessible to the Secretary and to appropriate federal law enforcement authorities and/or authorized local law enforcement authorities.

(3) In the event the Secretary authorizes more than one registering entity, or if otherwise necessary, the Secretary may require the establishment of a consolidated database to carry out the provisions of §72.6(c)(2).

(d) *Requests for agents.* (1) Prior to the transfer of any agent contained in Appendix A of this part, a CDC Form EA–101 must be completed for each transfer sought. As specified in CDC Form EA–101, the information provided must include:

(i) The name of the requestor and requesting facility;

(ii) The name of the transferor and transferring facility;

(iii) The names of the responsible facility officials for both the transferor and requestor;

(iv) The requesting facility's registration number;

(v) The transferring facility's registration number;

(vi) The name of the agent(s) being shipped;

(vii) The proposed use of the agent(s); and

(viii) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(2) The form must be signed by the transferor and requestor, and the responsible facility officials representing

both the transferring and requesting facilities.

(3) A copy of the completed CDC Form EA–101 must be retained by both transferring and requesting facilities for a period of five (5) years after the date of shipment or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

(4) All CDC forms EA–101 must be produced upon request to appropriate federal and authorized local law enforcement authorities, officials authorized by the Secretary, and officials of the registering entity.

(e) *Verification of registration.* (1) Prior to transferring any agent covered by this part, the transferor's responsible facility official must verify with the requestor's responsible facility official, and as appropriate, with the registering entity:

(i) That the requesting facility retains a valid, current registration;

(ii) That the requestor is an employee of the requesting facility; and

(iii) That the proposed use of the agent by the requestor is correctly indicated on CDC Form EA–101.

(2) In the event that any party is unable to verify the information required in paragraph (e)(1) of this section, or there is suspicion that the agent may not be used for the requested purpose, then the party shall immediately notify CDC.

(f) *Transfer.* (1) Upon completion of the CDC Form EA–101 and verification of registration, the transferring facility must comply with the packaging and shipping requirements in this part or other applicable regulations when transferring the agent.

(2) The requesting facility's responsible official must acknowledge receipt of the agent telephonically or otherwise electronically within 36 hours of receipt and provide a paper copy or facsimile transmission of receipt to the transferor within 3 business days of receipt of the agent.

(3) Upon telephonic acknowledgment of receipt of the agent, the transferor shall provide a completed paper copy or facsimile transmission of CDC Form EA–101 within 24 hours to the registering entity (holding that facility's registration), in accordance with §72.6(c)(2) for filing in a centralized repository.

(g) *Inspections.* (1) Registering entities or the Secretary may conduct random or for cause inspections of registered facilities to assure compliance with this part. All CDC forms EA–101 and records deemed relevant by inspecting officials must be produced upon request to authorized personnel conducting these inspections. Inspections may also include review of the mechanisms developed by a facility to track intrafacility transfers as well as the facility's agent disposal procedures.

(2) In addition, the Secretary may conduct inspections of registering entities, and/or any consolidated database established in accordance with §72.6(c)(3), to assure compliance with this part.

(h) *Exemptions*—(1) *Exemptions for certain select agents:* Select agents otherwise covered by this part are exempt from its provisions if:

(i) The agent is part of a clinical specimen intended for diagnostic, reference, or verification purposes. Isolates of covered agents from clinical specimens shall be disposed of in accordance with §72.6(i) after diagnostic, reference, or verification procedures have been completed;

(ii) The agent is a toxin having an LD_{50} for vertebrates of more than 100 nanograms per kilogram of body weight which is used for legitimate medical purposes or biomedical research or is one of the listed toxins which has been inactivated for use as a vaccine or otherwise detoxified for use in biomedical research procedures; or

(iii) The agent(s) is an exempted strain specified in Appendix A of this part and/or CDC Form EA–101. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents (Appendix A of this part). Individuals seeking additions to the list of exemptions should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future changes to the list of exemptions will be published in the

FEDERAL REGISTER for review and comment prior to inclusion on Appendix A of this part.

(2) *Exemption of CLIA certified laboratories:* Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. 263a) (CLIA), that utilize these select agents for diagnostic, reference, verification, or proficiency testing purposes are exempt from the provisions of § 72.6.

(3) *Procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory*: Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with the following provisions. (No additional paperwork on behalf of CLIA laboratories is required by this section.)

(i) Prior to transferring a select agent subject to this part to a CLIA laboratory for diagnostic, reference, verification, or proficiency testing purposes, the *transferor* must:

(A) Provide the following information on CDC Form EA–101:

(*1*) The name of the requestor and requesting facility;

(*2*) The name of the transferor and transferring facility;

(*3*) The name of the transferor's responsible facility official;

(*4*) The requesting facility's CLIA certification number (which the transferor must verify as valid and current with the registering entity);

(*5*) The transferring facility's registration number;

(*6*) The name of the agent(s) being shipped;

(*7*) The proposed use of the agent(s); and

(*8*) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Verify receipt of the agent with the CLIA laboratory and note such receipt on CDC Form EA–101;

(C) Transmit a copy of the form, signed by the transferror and the responsible facility official representing the transfering facility, to the registering entity holding the transferring facility's registration; and

(D) Retain a copy of CDC Form EA–101 in accordance with § 72.6(d)(3) and § 72.6(d)(4).

(ii) Prior to receiving a select agent listed in Appendix A of this part from a CLIA laboratory, the *requestor* must be registered in accordance with § 72.6(a) and comply with the following requirements:

(A) Provide the following information on the CDC Form EA–101:

(*1*) The name of the requestor and requesting facility;

(*2*) The name of the transferor and transferring facility;

(*3*) The name of the requestor's responsible facility official;

(*4*) The transferring facility's CLIA certification number;

(*5*) The requesting facility's registration number;

(*6*) The name of the agent(s) being shipped;

(*7*) The proposed use of the agent(s); and

(*8*) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Upon receiving the agent, note such receipt on CDC Form EA–101;

(C) Transmit a copy of CDC Form EA–101, signed by the requestor and the responsible facility official representing the requesting facility, to the registering entity holding the requesting facility's registration;

(D) Retain a copy of the CDC Form EA–101 in accordance with §§ 72.6(d)(3) and 72.6(d)(4);

(E) Comply with the disposal requirements of § 72.6(i) and all other sections of this part when subsequently transferring the agent.

(i) *Agent disposal.* (1) Upon termination of the use of the agent, all cultures and stocks of it will be

(i) Securely stored in accordance with prudent laboratory practices,

(ii) Transferred to another registered facility in accordance with this part, or

(iii) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

(2) When an agent, previously transferred to a facility in accordance with this part, is consumed or destroyed, the responsible facility official must formally notify the registering entity.

Formal notification must be noted on CDC Form EA–101 and a copy kept on record by the responsible facility official for a period of five (5) years and is subject to paragraph (g) of this section.

(j) *Definitions.* As used in this section:

Facility means any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a select agent subject to this part.

Registering entity means an organization or state agency authorized by the Secretary to register facilities as capable of handling select agents at Biosafety Level 2, 3, or 4, depending on the agent, in accordance with the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories."

Requestor means any person who receives or seeks to receive through any means a select agent subject to this part from any other person.

Responsible facility official means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility.

Secretary means the Secretary of the Department of Health and Human Services or her or his designee.

Select agent means a microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix A of this part. The term also includes:

(1) Genetically modified microorganisms or genetic elements from organisms on Appendix A of this part, shown to produce or encode for a factor associated with a disease, and

(2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A of this part, or their toxic submits.

Single geographic site means a building or complex of buildings at a single mailing address.

Transfer means:

(1) The conveyance or movement from a point or origination to a point of destination either:

(i) From one state or territory to another or;

(ii) Entirely within one contiguous state or territory.

(2) Intrafacility transfers within a registered facility located at a single geographic site are not covered by the provisions of §72.6 (d), (e), and (f) provided that:

(i) The intended use of the agent remains consistent with that specified in the most current transfer form; and

(ii) For each intrafacility transfer, the facility maintains records that include the name and location of the recipient; the amount of agent transferred, and the date transferred. Such records must be maintained for a period of five (5) years after the date of transfer or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

Transferor means any person who transfers or seeks to transfer through any means a select agent subject to this part to any other person.

[61 FR 55197, Oct. 24, 1996, as amended at 66 FR 45945, Aug. 31, 2001; 69 FR 18803, Apr. 9, 2004]

§72.7 Penalties.

Individuals in violation of this part are subject to a fine of no more than $250,000 or one year in jail, or both. Violations by organizations are subject to a fine or no more than $500,000 per event. A false, fictitious, or fraudulent statement or representation on the Government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.

[61 FR 55199, Oct. 24, 1996]

APPENDIX A TO PART 72—SELECT AGENTS

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus

8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus
Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP–12, Venezuelan Equine encephalitis virus strain TC–83, Yellow fever virus strain 17–D) are exempt.

Bacteria

1. *Bacillus anthracis*
2. *Brucella abortus, B. melitensis, B. suis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*
7. *Yersinia pestis*
Exemptions: vaccine strains as described in Title 9 CFR, 78.1 are exempt.

Rickettsiae

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi

1. *Coccidioides immitis*

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens epsilon toxin*
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin
Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD_{50} for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

RECOMBINANT ORGANISMS/MOLECULES

1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.

2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

OTHER RESTRICTIONS

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

ADDITIONAL EXEMPTIONS

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*) and the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*) are exempt.

2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the FEDERAL REGISTER for review and comment prior to inclusion in this Appendix.

[61 FR 55199, Oct. 24, 1996]

PART 73—SELECT AGENTS AND TOXINS

AUTHORITY: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a)

SOURCE: 67 FR 76896, Dec. 13, 2002, unless otherwise noted.

§73.0 Applicability and related requirements.

(a) For those entities that on February 7, 2003, were conducting activities under a certificate of registration issued under §72.6 of this chapter, or were lawfully possessing select agents and toxins, the provisions of part 73 and §72.6 of this chapter are applicable as follows:

(1) On and after February 7, 2003, the following sections are applicable: §§73.1 through 73.6 (definitions, purpose and scope, general prohibition, HHS select agents and toxins, overlap select agents and toxins, exemptions from requirements under this part); §73.9 (Responsible Official); §73.10 (Safety); §73.12 (emergency response); and §§73.15 through 73.21 (records; inspections; notification for theft, loss, or release; administrative review; civil money penalties; criminal penalties; and submissions and forms).

(2) On and after February 7, 2003, the provisions of §73.13 concerning training related to safety and emergency response are applicable; and on and after September 12, 2003, the remaining provisions of §73.13, including those concerning training related to security, are applicable.

(3) On and after March 12, 2003, the provisions of §73.14 (transfers) are applicable.

(4) On and after April 12, 2003, the provisions of §73.8 regarding security risk assessments for the entity, the Responsible Official, and any individual who owns or controls the entity are applicable; and on and after June 12, 2003, the remainder of §73.8 (including the provisions regarding individual risk assessments for other than the Responsible Official or any individual who owns or controls the entity) is applicable.

(5) On and after June 12, 2003, the provisions of §73.11 regarding the development of a security plan are applicable, and on and after September 12, 2003, the remainder of the provisions of §73.11, including the provisions regarding the implementation of a security plan, is applicable.

(6) On and after November 12, 2003, the provisions of §73.7 (registration) are applicable.

(b) The following also applies to those entities that on February 7, 2003, already were conducting activities under a certificate of registration issued under §72.6 of this chapter or already were lawfully possessing select agents and toxins:

(1) During the period from March 12, 2003, through November 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted to HHS or USDA an application package under §73.7 certifying compliance with the provisions referred to in paragraph (a)(1) of this section and the provisions in §73.13 concerning training related to safety and emergency response.

(2) During the period from March 12, 2003, through April 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted applications for approval under §73.8 (security risk assessment) to the Attorney General for the entity, the Responsible Official, and any individual who owns or controls the entity.

(3) During the period from April 12, 2003, through June 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted applications for approval under §73.8 (security risk assessments) to the Attorney General for all individuals (other than the Responsible Official and any individual who owns or controls the entity) with access to select agents and toxins.

(4) Such an entity remains:

(i) Subject to the registration provisions of §72.6 of this chapter until November 12, 2003, when superseded by §73.7;

(ii) Subject to the security provisions of §72.6 of this chapter regarding development of a security plan until June 12, 2003, when superseded by the requirement to develop a security plan under §73.11;

(iii) Subject to the security provisions of §72.6 of this chapter regarding implementation of a security plan until September 12, 2003, when superseded by the requirement to fully comply with §73.11;

(iv) Subject to the training provisions of §72.6 of this chapter related to security until September 12, 2003, when

superseded by the training provisions of §73.13 relating to security; and

(v) Subject to the transfer provisions of §72.6 of this chapter until March 12, 2003, when superseded by §73.14.

(5) A provisional registration certificate may be issued to an entity if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity; and

(ii) The entity otherwise meets all of the requirements of this Part.

(6) A provisional registration certificate will be effective until the Secretary either issues a certificate of registration or suspends or revokes the provisional registration.

(7) A provisional grant of access may be issued to an individual identified by an entity as having a legitimate need to have access to a select agent or toxin from whom, as of November 12, 2003, the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of that individual.

(8) A provisional grant of access will be effective until the Secretary either grants the individual access or denies access to a select agent or toxin.

(c) For those entities that on February 7, 2003, were not already were conducting activities under a certificate of registration issued under §72.6 of this chapter and were not already lawfully possessing select agents and toxins, the provisions of part 73 are applicable as follows:

(1) On and after February 7, 2003, the following sections are applicable: §§73.1 through 73.6 (definitions, purpose and scope, general prohibition, HHS select agents and toxins, overlap select agents and toxins, exemptions from requirements under this part); §§73.8 through 73.10 (Security risk assessments, Responsible Official, Safety); §§73.12 through 73.21 (emergency response, training, transfers, records; inspections; notification for theft, loss, or release; administrative review; civil money penalties; criminal penalties; and submissions and forms) and must hold a valid permit under 9 CFR part 122 and/or 42 CFR part 71.54.

(2) The provisions of §73.11 are applicable on and after September 12, 2003.

(3) On and after November 12, 2003, the provisions of §73.7 (registration) are applicable.

(4) During the period from February 7, 2003, through November 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted to HHS or USDA an application package under §73.7 certifying compliance with the provisions referred to in paragraph (b)(2) of this section.

(5) A provisional registration certificate may be issued to an entity if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity;

(ii) The entity otherwise meets all of the requirements of this Part; and

(iii) The HHS Secretary finds that circumstances warrant such action in the interest of the public health and safety or national security.

(6) A provisional registration certificate will be effective until the Secretary either issues a certificate of registration or suspends or revokes the provisional registration.

(7) A provisional grant of access may be issued to an individual identified by an entity as having a legitimate need to have access to a select agent or toxin from whom, as of November 12, 2003, the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of that individual.

(8) A provisional grant of access will be effective until the Secretary either grants the individual access or denies access to a select agent or toxin.

[67 FR 76896, Dec. 13, 2002, as amended at 68 FR 62246, Nov. 3, 2003]

§73.1 Definitions.

For purposes of this part:

Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae,

or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

CDC means Centers for Disease Control and Prevention of the Department of Health and Human Services.

Diagnosis means the analysis of specimens for the purpose of identifying or confirming the presence of a listed select agent *or toxin* provided that such analysis is directly related to protecting the public health or safety.

Entity means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

HHS means the Department of Health and Human Services.

HHS Secretary means the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent or toxin means a biological agent or toxin included in § 73.4.

Overlap select agent or toxin means a biological agent or toxin included in § 73.5.

Proficiency testing means a sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated.

Principal investigator means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Select agent or toxin or *select agent and toxin* without identification as HHS or overlap means all of those biological agents or toxins included in §§ 73.4 and 73.5 of this part.

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States means the United States of America, the District of Columbia, Puerto Rico, and the territories and possessions of the United States.

USDA means the United States Department of Agriculture.

USDA Secretary means the Department of Agriculture or his or her designee, unless otherwise specified.

Verification means the processes required to assure the accuracy, precision, and the analytical sensitivity and specificity of any procedure used for diagnosis.

§ 73.2 Purpose and scope.

(a) This part sets forth requirements regarding the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents and toxins. The requirements are designed to implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188). The Act was designed to provide protection against the effects of misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The agents and toxins subject to requirements under this part are those that have the potential to pose a severe threat to public health and safety. They are further identified as either HHS select agents and toxins or overlap select agents and toxins. The term HHS select agents and toxins refers to those select agents and toxins subject to these regulations but not subject to USDA requirements at 9 CFR part 121. The overlap group consists of those select agents and toxins subject to requirements promulgated by the HHS Secretary under this part

and also subject to corresponding requirements promulgated by USDA at 9 CFR part 121.

(b) This part does not set requirements for the exportation of select agents or toxins. The Department of Commerce has primary responsibility for regulating the exportation of microorganisms and toxins in Title 15 of the Code of Federal Regulations.

(c) This part does not set requirements for the transportation in commerce of select agents or toxins. The Department of Transportation has primary responsibility for regulating the transportation of such select agents and toxins as hazardous materials under 49 CFR parts 171 through 180.

§ 73.3 General prohibition.

An entity or individual may not possess or use in the United States, receive from outside the United States, or transfer within the United States, a select agent or toxin unless such activities are conducted for a lawful purpose and in accordance with the provisions of this part. Registration, exclusions, and exemptions are automatically revoked when any event occurs that results in an entity or individual no longer being eligible.

§ 73.4 HHS select agents and toxins.

Except for exclusions under paragraph (f) of this section, the viruses, bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms specified in paragraphs (a) through (e) of this part are HHS select agents and toxins.

(a) Viruses:

(1) Crimean-Congo haemorrhagic fever virus.

(2) Ebola viruses.

(3) Cercopithecine herpesvirus 1 (Herpes B virus).

(4) Lassa fever virus.

(5) Marburg virus.

(6) Monkeypox virus.

(7) South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito).

(8) Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever]).

(9) Variola major virus (Smallpox virus) and Variola minor virus (Alastrim).

(b) Bacteria:

(1) *Rickettsia prowazekii.*

(2) *Rickettsia rickettsii.*

(3) *Yersinia pestis.*

(c) Fungi: *Coccidioides posadasii.*

(d) Toxins:

(1) Abrin.

(2) Conotoxins.

(3) Diacetoxyscirpenol.

(4) Ricin.

(5) Saxitoxin.

(6) Tetrodotoxin.

(7) Shiga-like ribosome inactivating proteins.

(e) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids:

(i) Are in a vector or host chromosome;

(ii) Can be expressed *in vivo* or *in vitro*; or

(iii) Are in a vector or host chromosome and can be expressed *in vivo* or *in vitro.*

(3) Viruses, bacteria, fungi, and toxins listed in paragraphs (a) through (d) of this section that have been genetically modified.

(f) Exclusions:

(1) This section does not include any select agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) This section does not include nonviable select agent organisms or nonfunctional toxins.

(3) Paragraph (a) of this section does not include the vaccine strain of Junin virus (Candid #1).

(4) Paragraph (d) of this section does not include the following toxins (in the purified form or in combinations of

pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 100 mg of Abrin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; or 100 mg of Tetrodotoxin.

(5) The HHS Secretary may exclude from this section attenuated strains of HHS select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety. To apply for an exclusion an applicant must submit a request in writing in accordance with §73.21 to the HHS Secretary establishing that the attenuated strain or toxin is eligible for exclusion. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. An exclusion will be effective upon notification to the applicant. Exclusions will be published in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site at *http://www.cdc.gov*. Exclusions also will be referenced in this section when changes are made based on periodic reviews.

§ 73.5 Overlap select agents and toxins.

Except for exclusions under paragraph (f) of this section, the viruses, bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms specified in paragraphs (a) through (e) of this part are overlap select agents and toxins.

(a) Viruses:

(1) Eastern Equine Encephalitis virus.

(2) Nipah and Hendra Complex viruses.

(3) Rift Valley fever virus.

(4) Venezuelan Equine Encephalitis virus.

(b) Bacteria:

(1) *Bacillus anthracis.*

(2) *Brucella abortus.*

(3) *Brucella melitensis.*

(4) *Brucella suis.*

(5) *Burkholderia mallei* (formerly *Pseudomonas mallei*).

(6) *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*).

(7) Botulinum neurotoxin producing species of *Clostridium.*

(8) *Coxiella burnetii.*

(9) *Francisella tularensis.*

(c) Fungi: *Coccidioides immitis.*

(d) Toxins:

(1) Botulinum neurotoxins.

(2) *Clostridium perfringens* epsilon toxin.

(3) Shigatoxin.

(4) Staphylococcal enterotoxins.

(5) T–2 toxin.

(e) Genetic elements, recombinant nucleic acids, and recombinant organisms:

(1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids:

(i) Are in a vector or host chromosome;

(ii) Can be expressed *in vivo* or *in vitro*; or

(iii) Are in a vector or host chromosome and can be expressed *in vivo* or *in vitro.*

(3) Viruses, bacteria, fungi, and toxins listed in paragraphs (a) through (d) of this section that have been genetically modified.

(f) Exclusions:

(1) This section does not include any select agent or toxin that is in its naturally occurring environment provided that it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) This section does not include nonviable select agent organisms or nonfunctional toxins.

(3) Paragraph (a) does not include the vaccine strain of Rift Valley fever virus (MP–12) or Venezuelan Equine encephalitis virus vaccine strain TC–83.

(4) Paragraph (d) of this section does not include the following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 0.5 mg of Botulinum neurotoxins; 5 mg of

Staphylococcal enterotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Shigatoxin; or 1,000 mg of T–2 toxin.

(5) The HHS Secretary, after consultation with the USDA Secretary, may exclude from this section attenuated strains of overlap select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety and do not meet the criteria in 9 CFR part 121 for inclusion. To apply for an exclusion, an applicant must submit a request in writing in accordance with §73.21 to the HHS Secretary or the USDA Secretary in accordance with 9 CFR part 121, establishing that the attenuated strain is eligible for exclusion. In response to an application submitted to the HHS Secretary, the HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. An exclusion will be effective upon notification to the applicant. Exclusions will be published in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site at *http://www.cdc.gov*. Also, they will be referenced in this section when changes are made based on periodic reviews.

§73.6 Exemptions from requirements under this part.

(a) An entity is exempt from the provisions of this part, other than §73.14 (transfer), provided that all of the following apply:

(1) The only activities conducted by the entity that are subject to this part concern select agents or toxins that are contained in specimens or in isolates from specimens presented for diagnosis, verification, or proficiency testing;

(2) Upon identification of a select agent or toxin as the result of diagnosis or verification, the entity immediately reports to the HHS Secretary by telephone, facsimile, or e-mail in accordance with §73.21 any of the following: Variola major virus (Smallpox virus) and Variola minor (Alastrim), *Bacillus anthracis, Yersinia pestis,* Botulinum neurotoxins, *Francisella tularensis,* Ebola viruses, Marburg virus, Lassa fever virus, and South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito);

(3) The entity reports as required under Federal, State, or local law, to appropriate authorities;

(4) After the diagnosis, verification, or proficiency testing, the entity either transfers the specimens or isolates containing a select agent or toxin from the specimens to a facility eligible for receiving them under this part, or destroys them on-site by autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation;

(5) The entity transfers or destroys those select agents or toxins used for diagnosis or testing within seven days after identification, unless directed otherwise by the Federal Bureau of Investigation or other law enforcement entity after consultation with the HHS Secretary; and

(6) The entity transfers or destroys those select agents or toxins used for proficiency testing within 90 days after receipt; and

(7) The entity prepares a record of the identification and transfer or destruction on CDC Form 0.1318, submits the completed form to the HHS Secretary in accordance with §73.21 within seven days after identification, and maintains a copy of the record for a period of three years.

(b) Unless the HHS Secretary issues an order to an entity making specific provisions of this part applicable to protect the public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use is only for the approved purpose and meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262);

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq*).

(c) The HHS Secretary may exempt from the requirements of this part on a case-by-case basis an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section and additional regulation under this part is not necessary to protect public health and safety. To apply for an exemption an applicant must submit to the HHS Secretary in accordance with §73.21 a completed CDC Form 0.1317 certifying that the product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section, and that additional regulation under this part is not necessary to protect public health and safety. The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. The applicant must notify the HHS Secretary when an authorization for an investigation no longer exists. This exemption automatically ceases when such authorization is no longer in effect.

(d) The HHS Secretary may temporarily exempt an entity from the requirements of this part, in whole or in part, based on a determination that the exemption is necessary to provide for the timely participation of the entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 days, except that the HHS Secretary may grant one extension of an additional 30 days. To apply for an exemption or an extension of an exemption, an applicant must submit to the HHS Secretary in accordance with §73.21 a completed CDC Form 0.1317 establishing the need to provide for the timely participation of the entity in a response to a domestic or foreign public health emergency. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.

(e) Upon request of the USDA Secretary, after the USDA Secretary has granted an exemption under section 212(g)(1)(D) of the Agricultural Bioterrorism Protection Act of 2002 based on a finding that there is an agricultural emergency, the HHS Secretary may temporarily exempt an entity from the applicability of the requirements of this part, in whole or in part, to provide for the timely participation of the entity in response to the agricultural emergency. With respect to the emergency, the exemption under this part may not exceed 30 days, except that upon the request of the USDA Secretary, the HHS Secretary may grant one extension of an additional 30 days.

§73.7 Registration.

(a) An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless the entity has been granted a certificate of registration by the HHS Secretary or the USDA Secretary.

(b) To apply for a certificate of registration an entity must:

(1) Obtain a registration application number from the HHS Secretary and then apply for approval under §73.8 for the entity, the Responsible Official, and any individual who owns or controls the entity; and

(2) In accordance with §73.21, submit the information requested to the HHS Secretary or the USDA Secretary as specified in the registration application package [CDC Form 0.1319]. Information submitted will be used to determine whether the applicant would be eligible to conduct activities under this part. Minimum information required includes:

(i) Identification information (e.g., name, address, contact numbers, identification number assigned by the Attorney General for compliance with §73.8);

(ii) The name, source, and characterization information on select agents and toxins included in the registration, and quantities held at the time of the application;

(iii) The location, including building and room and floor plans for each building and room, where each select agent or toxin will be stored or used;

(iv) Information addressing safety, security, emergency response plans, and training, including descriptions of any equivalent measures adopted pursuant to §73.11(d);

(v) The name, position, and identification information regarding the Responsible Official, including the identification number assigned by the Attorney General for compliance with §73.8;

(vi) A list of individuals who will need access to select agents and toxins;

(vii) A certification statement signed by the Responsible Official attesting to the accuracy of the information submitted; and

(viii) Any other information necessary for the determination.

(c) An application that covers any HHS select agents or toxins (regardless of whether it also covers overlap select agents or toxins) must be submitted to the HHS Secretary in accordance with §73.21. An application that covers only overlap select agents or toxins may be submitted to either the HHS Secretary or the USDA Secretary.

(d) A certificate of registration will be valid only for the specific select agents and toxins, and the specified activities and locations that are consistent with the information provided by the entity upon which the certificate of registration or amendment was granted. The Responsible Official must promptly notify the HHS Secretary in writing in accordance with §73.21, if a change occurs in any information submitted to the HHS Secretary in the application for the certificate of registration or amendments. This includes modifications to the list of individuals approved under §73.8, changes in area of work, or changes in protocols or objectives of studies. To apply for an amendment to a certificate of registration to add select agents or toxins or to change specified activities or locations, an entity must obtain the relevant portion of the registration application package and submit the information requested in the package to the agency that issued the certificate of registration. The package must be submitted to the appropriate address specified in the package.

(e) In response to an application to the HHS Secretary for a certificate of registration or amendment for select agents and toxins, the HHS Secretary will issue a certificate of registration or amendment if it is determined that the stated activities would be lawful (based on information submitted by the applicant or otherwise obtained by the HHS Secretary) and meet the requirements of this part. Otherwise, the application for a certificate of registration or amendment will be denied. The HHS Secretary will issue a certificate of registration or amendment for an overlap select agent or toxin only if the USDA Secretary concurs that the requirements for obtaining a certificate of registration or amendment under 9 CFR part 121 have been met. The determination of whether a certificate of registration or amendment will be granted may be contingent upon inspection or submission of additional information.

(f) A certificate of registration will cover activities at only one general physical location (a building or a complex of buildings at a single mailing address).

(g) Unless terminated sooner in accordance with this paragraph, a certificate of registration will be valid for up to three years. To obtain a new certificate of registration an entity must submit a new application. (Note: To help ensure timely processing of an application for a certificate of registration or amendment, the applicant should submit the application at least eight weeks prior to the expiration date.)

(1) The HHS Secretary will terminate a certificate of registration based on a determination that the recipient no longer conducts activities covered by the certificate.

(2) Also, the HHS Secretary may terminate a certificate of registration based on a security risk assessment under §73.8 or failure to comply with the provisions of this part, and may take such action immediately if necessary to protect the public health or safety. Upon such termination, any select agent or toxin in the possession of

the entity must be destroyed or transferred as directed by the HHS Secretary.

(h) An entity must provide notice in writing to the HHS Secretary in accordance with §73.21 at least five business days before destroying a select agent or toxin, if the destruction would be for the purpose of discontinuing activities with a select agent or toxin covered by a certificate of registration. This will allow the HHS Secretary to observe the destruction or take other action as appropriate.

§73.8 Security risk assessment.

(a) An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless approved by the HHS Secretary or the USDA Secretary based on a security risk assessment by the Attorney General. This paragraph does not apply to Federal, State, or local governmental agencies, but does apply to the Responsible Official and others working for or otherwise acting on behalf of such agencies.

(b) An entity may not provide an individual access to a select agent or toxin and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or the USDA Secretary, based on a security risk assessment by the Attorney General.

(c) To obtain a security risk assessment under this section, an entity must submit to the Attorney General the information requested for the entity, the Responsible Official, any individual who owns or controls the entity, and any other individuals required to obtain approval under this section. The determinations regarding approval will be made by the agency that is responsible for making determinations regarding the corresponding certificate of registration. An entity will receive prompt notice of action taken in response to a request for approval for the entity, the Responsible Official, and individuals. An individual will receive prompt notice of a denial of approval.

(d) The Attorney General will conduct a security risk assessment on entities and individuals whose identifying information is properly submitted. Based on the security risk assessment, the Attorney General will notify the HHS Secretary if the Attorney General identifies any entity, individual who owns or controls the entity, or any other individual who is:

(1) A restricted person under 18 U.S.C. 175b; or

(2) Reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime specified in 18 U.S.C. 2332b(g)(5);

(ii) Having a knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).

(e) The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as a restricted person under paragraph (d)(1). The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as meeting the criteria of paragraph (d)(2) unless determined by the HHS Secretary to be warranted in the interest of the public health and safety or national security. For individuals meeting the criteria of paragraph (d)(2) the HHS Secretary may provide a limited approval for a specified time based upon the finding that circumstances warrant such action in the interest of the public health and safety or national security.

(f) Unless a shorter period is granted under paragraph (e) of this section, an approval for an entity or individual under this section will be valid for five years unless terminated sooner. The HHS Secretary may terminate an approval for an entity or an individual based on a request from the entity or individual, a security risk assessment under this section, or a failure to comply with the provisions of this part, and may take such action immediately if necessary to protect the public health and safety, or national security.

(g) The HHS Secretary will request the Attorney General to expedite the review process for an individual and will take action to expedite the HHS

Secretary's review process for an individual upon a showing of good cause (e.g., public health or agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher). To apply for an expedited review, an entity must submit a request in writing in accordance with §73.21 to the HHS Secretary establishing the need for such action. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.

§73.9 Responsible Official.

(a) As a condition of conducting activities regulated under this part, an entity must identify and authorize an individual as the Responsible Official. The Responsible Official may identify one or more individuals, any of whom may serve as the Alternate Responsible Official when the Responsible Official is unavailable. The Responsible Official and all individuals identified to serve as the Alternate Responsible Official must meet all of the qualifications for a Responsible Official. The Responsible Official and all Alternate Responsible Officials must:

(1) Be approved under §73.8;

(2) Be familiar with the requirements of this part; and

(3) Have authority and responsibility to ensure that the requirements of this part are met, on behalf of the entity.

(b) For purposes of this part, the Alternate Responsible Official acting in the absence of the Responsible Official may conduct all of those activities required under this part to be performed by the Responsible Official.

(c) The Responsible Official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing safety, security and emergency response plans in accordance with §73.10—§73.12;

(2) Allowing only approved individuals to have access to select agents or toxins in accordance with §73.8 and §73.11;

(3) Providing appropriate training for safety, security and emergency response in accordance with §73.13;

(4) Transferring select agents or toxins in accordance with §73.14;

(5) Providing timely notice of any theft, loss, or release of a select agent or toxin in accordance with §73.13;

(6) Maintaining detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins in accordance with §73.15.

(7) The reporting of the identification of a select agent or toxin as a result of diagnosis, verification or proficiency testing in accordance with §73.6.

§73.10 Safety.

(a) An entity subject to the provisions of this part, must develop and implement a safety plan. In developing a safety plan, an entity should consider:

(1) The biosafety standards and requirements for BSL 2, 3, or 4 operations, as they pertain to the respective select agents, that are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," including all appendices except Appendix F. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh, Pennsylvania, 75250–7954 or call in the Washington, DC metropolitan area 202–512–1800 or outside that area call toll free 1–866–512–1800. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia. This publication is also available on the CDC Web site at *http://www.cdc.gov*.

(2) The specific requirements for handling toxins found in 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories" and/or 29 CFR 1910.1200, "Hazard Communication," whichever applies and specific provisions for handling toxins found in Appendix I in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories,"

(3) For provisions of the safety plan relating to genetic elements, recombinant nucleic acids and recombinant organisms, the "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). This includes, among other things, provisions regarding risk assessment, physical containment, biological containment, and local review and applies to all recombinant DNA research, regardless of

funding. Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia, 30333. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia. The "NIH Guidelines for Research Involving Recombinant DNA Molecules," is also available on the CDC Web site at *http://www.cdc.gov*.

(b) The Responsible Official or his or her designee must conduct regular inspections (at least annually) of the laboratory where select agents and toxins are stored or used to ensure compliance with all of the procedures and protocols of the safety plan. The results of these inspections must be documented, and any deficiencies identified during inspections must be corrected.

(c) An entity may not conduct the following experiments unless approved by the HHS Secretary after consultation with experts:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.

(d) [Reserved]

§73.11 Security.

(a) An entity must develop and implement a security plan establishing policy and procedures that ensure the security of areas containing select agents and toxins. The security plan must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated with a security systems approach.

(b) The plan must:

(1) Describe inventory control procedures, minimal education and experience criteria for those individuals with access to select agents or toxins, physical security, and cyber security;

(2) Contain provisions for routine cleaning, maintenance, and repairs; provisions for training personnel in security procedures; provisions for securing the area (e.g., card access, key pads, locks) and protocols for changing access numbers or locks following staff changes;

(3) Describe procedures for loss or compromise of keys, passwords, combinations, etc.;

(4) Contain procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or alteration of inventory records;

(5) Contain provisions for the control of access to containers where listed agents and toxins are stored; and procedures for reporting and removing unauthorized persons;

(6) Contain provisions for ensuring that all individuals with access, including workers and visitors, understand security requirements and are trained and equipped to follow established procedures;

(7) Establish procedures for reporting and removing unauthorized persons; and

(8) Establish procedures for securing the area when individuals approved under §73.8 are not present (e.g., card access system, key pads, locks), including protocols for changing access numbers or locks following staff changes.

(c) The security plan must be reviewed by the RO at least annually and after any incident.

(d) With respect to areas containing select agents and toxins, the entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

(1) Allow unescorted access only to individuals who have been approved under §73.8 and who are performing a specifically authorized function during hours required to perform the defined job (including delivery to an outside shipping agent for transportation in commerce);

(2) Allow individuals not approved under §73.8 to conduct routine cleaning, maintenance, repairs, and other

non-laboratory functions only when escorted and continually monitored by individuals approved under § 73.8;

(3) Provide for the control of access to containers where select agents and toxins are stored by requiring freezers, refrigerators, cabinets, and other containers where stocks of select agents and toxins are stored to be locked (e.g., card access system, lock boxes) when they are not in the direct view of approved staff, and by using other monitoring measures as needed, such as video surveillance;

(4) Require the inspection of all packages upon entry to and exit from the area;

(5) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging, and movement from a laboratory to another laboratory or from a laboratory to a shipping place, is conducted under the supervision of an individual approved under § 73.8;

(6) Require that each approved individual under 73.8 does not share with any other person, his or her unique means (e.g., keycards or passwords) of accessing the area or select agent or toxin;

(7) Require that each individual approved under § 73.8 report any of the following immediately to the Responsible Official:

(i) Any loss or compromise of their keys, passwords, combinations, etc.;

(ii) Any suspicious persons or activities;

(iii) Any loss or theft of select agents or toxins;

(iv) Any release of select agents or toxins; and

(v) Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.

(e) The entity must separate areas where select agents and toxins are stored or used from the public areas of the buildings.

(f) Upon termination of the use, a select agent or toxin must be

(1) Securely stored in accordance with the requirements of this section;

(2) Transferred to another registered facility in accordance with § 73.14; or

(3) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

§ 73.12 Emergency response.

(a) An entity required to register under this part must develop and implement an emergency response plan that meets the requirements of OSHA Hazardous waste operations and emergency response standard at 29 CFR 1910.120. Nothing in this section is to supersede or preempt the enforcement of the emergency response requirements imposed by the other statute or regulation.

(b) The emergency response plan must be coordinated with any entity-wide plans. The plan must address such events as bomb threats, severe weather (hurricanes, floods), earthquakes, power outages, and other natural disasters or emergencies.

(c) The emergency response plan must address the following:

(1) The hazards associated with the use of the select agents and toxins;

(2) Any hazards associated with response actions that could lead to a spread of a select agent or toxin;

(3) Planning and coordination with outside parties;

(4) Personnel roles, lines of authority, training, and communication;

(5) Emergency recognition and prevention;

(6) Safe distances and places of refuge;

(7) Site security and control;

(8) Evacuation routes and procedures;

(9) Decontamination;

(10) Emergency medical treatment and first aid;

(11) Emergency alerting and response procedures;

(12) Critique of response and follow-up;

(13) Personal protective and emergency equipment; and

(14) Special procedures needed to address the hazards of specific agents.

§ 73.13 Training.

(a) An entity required to register under this part and falls outside of the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030(a) must provide information and training on safety and security for working with select agents

and toxins to each individual approved for access under § 73.8 and each unapproved individual working in, or visiting, areas where select agents and toxins are handled or stored. The information and training must meet the requirements of this section and must ensure that all individuals who work in, or visit, the areas understand the hazards of select agents and toxins present in the area.

(b) The entity must provide information and training at the time of an individual's initial assignment to a work area where select agents or toxins are present and prior to assignments involving new exposure situations. The entity must provide refresher training annually.

(c) The Responsible Official must provide appropriate training in safety, containment, and security to all individuals with access to areas where select agents and toxins are handled or stored.

(d) In lieu of initial training for those individuals already involved in handling select agents or toxins, the Responsible Official may certify in writing that the individual has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities.

(e) The entity must ensure that each individual with access to areas where select agents or toxins are handled or stored received and understood the training required by this section unless certified under paragraph (d) of this section. The entity must record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training.

§ 73.14 Transfers.

A select agent or toxin may not be transferred from one entity to another entity within the United States (regardless of whether the transfer is interstate or intrastate), or received by an entity in the United States from an entity outside the United States, unless:

(a) The sender:

(1) Has a certificate of registration that covers the transfer of the particular select agent or toxin to be transferred,

(2) Meets the exemption requirements under § 73.6 (a) for the particular select agent or toxin to be transferred, or

(3) Is transferring the select agent or toxin from outside the United States (and all import requirements are met);

(b) The recipient has a certificate of registration that includes the particular select agent or toxin to be transferred;

(c) Prior to the transfer, the recipient and sender completes CDC Form EA–101, and the recipient submits to the HHS Secretary in accordance with § 73.21 a completed CDC Form EA–101.

(d) CDC has authorized the transfer based on the finding that the recipient has a certificate of registration covering the transfer of the select agent or toxin;

(e) The sender complies with all applicable laws concerning packaging and shipping;

(f) The Responsible Official of the recipient provides a completed paper copy or facsimile transmission of CDC Form EA–101 to the sender and to the HHS Secretary within 2 business days of receipt of the select agent or toxin; and

(g) The recipient immediately reports to the HHS Secretary if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package received containing select agents or toxins has been leaking or was otherwise damaged.

(h) When the select agents or toxins are consumed or destroyed after a transfer, the recipient must within five business days report such fact to the HHS Secretary in accordance with § 73.21 on a CDC Form EA–101.

NOTE TO § 73.14: This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

§ 73.15 Records.

The Responsible Official must maintain complete records relating to the activities covered by this Part. Such records include:

(a) An entity required to register under this part must maintain an up-to-date, accurate list of the individuals approved under § 73.8 for access to select agents and toxins.

(b) The entity must maintain an accurate, current inventory of each select agent and toxin held. The inventory records must include the following information for each select agent and toxin:

(1) The name, characteristics, and source data;

(2) The quantity held on the date of the first inventory (toxins only);

(3) The quantity acquired, the source, and date of acquisition;

(4) The quantity, volume, or mass destroyed or otherwise disposed of and the date of each such action;

(5) The quantity used and date(s) of the use (toxins only);

(6) The quantity transferred, the date of transfer, and individual to whom it was transferred (this includes transfers within an entity when the sender and the recipient are covered by the same certificate of registration);

(7) The current quantity held (toxins only);

(8) Any select agent or toxin lost, stolen, or otherwise unaccounted for; and

(9) A written explanation of any discrepancies.

(c) The entity must maintain the following records:

(1) For access to the select agents or toxins:

(i) The name of each individual who has accessed any select agent or toxin;

(ii) The select agent or toxin used;

(iii) The date when the select agent or toxin was removed, if removed from long-term storage or holdings for stock cultures;

(iv) The quantity removed (toxins only);

(v) The date the select agent or toxin was returned to the long-term storage or holdings for stock cultures; and

(vi) The quantity returned (toxins only);

(2) For access to the area where select agents are used or stored:

(i) The name of each individual who has accessed the area;

(ii) The date and time the individual entered the area;

(iii) The date and time the individual left the area; and

(iv) For individuals not approved under §73.8, the individual approved under §73.8 who accompanied the unapproved individual into the area.

(d) The entity must implement a system to ensure that all records and databases created under paragraphs (b) and (c) of this section are accurate, and that the authenticity of records may be verified.

(e) The entity must create a record concerning inspections conducted under §73.10(b).

(f) Safety, security, and emergency response plans.

(g) Training records.

(h) Transfer documents (CDC Form EA–101) and permits.

(i) Safety and security incident reports.

(j) The entity must maintain all records created under this part for three years.

§73.16 Inspections.

The HHS Secretary, without prior notification and with or without cause, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

§73.17 Notification for theft, loss, or release.

(a) Upon discovery of a theft or loss of a select agent or toxin, an entity required to register under this part must immediately notify the HHS Secretary and State and local law enforcement. The notification must be reported to the HHS Secretary by either telephone, facsimile, or e-mail in accordance with §73.21.

(b) Thefts or losses must be reported whether the select agent or toxin is subsequently recovered or the responsible parties are identified.

(c) When reporting a theft or loss, the entity must provide the following information:

(1) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);

(2) An estimate of the quantity lost or stolen;

(3) An estimate of the time during which the theft or loss occurred; and

(4) The location (building, room) from which the theft or loss occurred.

(d) The entity shall immediately notify the HHS Secretary and State and local public health agencies of any release of a select agent or toxin causing occupational exposure or release outside of the primary containment barriers. The report must be made to the HHS Secretary by telephone, facsimile, or e-mail in accordance with § 73.21.

(e) When reporting a release, the entity must provide the following information:

(1) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);

(2) An estimate of the quantity released;

(3) The time and duration of the release;

(4) The environment into which the release occurred (e.g., in building or outside of building, waste system);

(5) The location (building, room) from which the release occurred;

(6) The number of individuals potentially exposed at the facility.

(7) Actions taken to respond to the release; and

(8) Hazards posed by the release.

(f) Within seven calendar days of theft, loss, or release, the entity must submit a follow-up report in writing to the HHS Secretary on CDC Form 0.1316 in accordance with § 73.21.

§ 73.18 Administrative review.

An entity may obtain review of a decision denying or revoking a certificate of registration under § 73.7 and the affected entity or individual may obtain review of a decision denying or revoking approval under § 73.8 by requesting such review in writing within 30 calendar days after the adverse decision. The request for review must state the factual basis for the review, which will be carried out in accordance with 42 U.S.C. 262a(e)(7). Where the adverse decision is in whole or in part based upon notification by the Attorney General under 42 U.S.C. 262a (e)(3), the request for review will be forwarded to the Attorney General for the Attorney General's review and final notification to the HHS Secretary.

§ 73.19 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigation and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violation of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board (DAB) have been delegated authority to conduct hearings and to render decisions with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The DAB of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.

§ 73.20 Criminal penalties.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) provides specific criminal penalties for violation of provisions of this part. This is in addition to any other criminal penalties that would apply for violation of provisions of this part.

§ 73.21 Submissions and forms.

(a) CDC forms referred to in this part, including registration application packages, may be obtained on the Select Agent Program Web site at *http://www.cdc.gov,* or by requesting them in

writing from the Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mail Stop E 79, Atlanta, Georgia 30333. Forms (including any required attachments) must be submitted in accordance with the instructions on the form.

(b) Applications, requests, notifications, and other information required to be submitted to the HHS Secretary in writing, but not required to be on a form, unless otherwise specified, must be submitted to the Select Agent Program, Center for Disease Control and Prevention, 1600 Clifton Road, NE., Mail Stop E 79, Atlanta, Georgia 30333, or by e-mail at *lrsat@cdc.gov*.

(c) Information not required to be submitted to the HHS Secretary on a form may be submitted to the Select Agent Program, Center for Disease Control and Prevention, 1600 Clifton Road, NE., Mail Stop E 79, Atlanta, Georgia 30333, or by e-mail at *lrsat@cdc.gov*.

(d) If an application or request submitted to the HHS Secretary is incomplete or additional information is needed to allow the decision maker to make a determination, the HHS Secretary will notify the applicant or requester in writing of the deficiency and request additional information. If the applicant or requester fails to respond within 30 calendar days (or within such time period agreed upon by the applicant or requester and the HHS Secretary) the application or request will be deemed abandoned.

(e) You may request forms or other information from the USDA at the following address: APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 40, Riverdale, MD 20737–1231.

PART 75—STANDARDS FOR THE ACCREDITATION OF EDUCATIONAL PROGRAMS FOR AND THE CREDENTIALING OF RADIOLOGIC PERSONNEL

Sec.

AUTHORITY: Sec. 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, Pub. L. 97–35, 95 Stat. 599–600 (42 U.S.C. 10004).

SOURCE: 50 FR 50717, Dec. 11, 1985, unless otherwise noted.

§ 75.1 Background and purpose.

(a) The purpose of these regulations is to implement the provisions of section 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10004, which requires the establishment by the Secretary of Health and Human Services of standards for the accreditation of programs for the education of certain persons who administer radiologic procedures and for the credentialing of such persons.

(b) Section 979 requires the Secretary, after consultation with specified Federal agencies, appropriate agencies of States, and appropriate professional organizations, to promulgate by regulation the minimum standards described above. These standards distinguish between the occupations of (1) radiographer, (2) dental hygienist, (3) dental assistant, (4) nuclear medicine technologist, and (5) radiation therapy technologist. In the interest of public safety and to prevent the hazards of improper use of medical radiation identified by Congress in its determination of the need for standards, the Secretary is also authorized to prepare standards for other occupational groups utilizing ionizing and non-ionizing radiation as he/she finds appropriate. However, the standards set out below are limited to the five occupational groups listed above, utilizing

ionizing radiation. Nothing in these accreditation standards is intended to discriminate against proprietary schools.

§ 75.2 Definitions.

All terms not defined herein shall have the meaning given them in the Act. As used in this part:

Accreditation, as applied to an educational program, means recognition, by a State government or by a nongovernmental agency or association, of a specialized program of study as meeting or exceeding certain established qualifications and educational standards. As applied to a health care or educational institution, *accreditation* means recognition, by a State government or by a nongovernmental agency or association, of the institution as meeting or exceeding certain established standards or criteria for that type of institution.

Act means the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10001–10008.

Continuing competency means the maintenance of knowledge and skills and/or demonstrated performance that are adequate and relevant to professional practice needs.

Credentialing means any process whereby a State Government or nongovernmental agency or association grants recognition to an individual who meets certain predetermined qualifications.

Dental hygienist means a person licensed by the State as a dental hygienist.

Dental assistant means a person other than a dental hygienist who assists a dentist in the care of patients.

Educational program means a set of formally structured activities designed to provide students with the knowledge and skills necessary to enter an occupation, with evaluation of student performance according to predetermined objectives.

Energized laboratory means any facility which contains equipment that generates ionizing radiation. This does not include facilities for training students when the equipment is not powered to emit ionizing radiation, e.g., practice in setting controls and positioning of patients.

Formal training means training or education, including either didactic or clinical practicum or both, which has a specified objective, planned activities for students, and suitable methods for measuring student attainment, and which is offered, sponsored, or approved by an organization or institution which is able to meet or enforce these criteria.

Ionizing radiation means any electromagnetic or particulate radiation (X-rays, gamma rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles) which interacts with atoms to produce ion pairs in matter.

Licensed practitioner means a licensed doctor of medicine, osteopathy, dentistry, podiatry, or chiropractic.

Licensure means the process by which an agency of State government grants permission to persons meeting predetermined qualifications to engage in an occupation.

Nuclear medicine technologist means a person other than a licensed practitioner who prepares and administers radio-pharmaceuticals to human beings and conducts *in vivo* or *in vitro* detection and measurement of radioactivity for medical purposes.

Permit means an authorization issued by a State for specific tasks or practices rather than the entire scope of practice in an occupation.

Radiation therapy technologist means a person other than a licensed practitioner who utilizes ionizing radiation-generating equipment for therapeutic purposes on human subjects.

Radiographer means an individual other than a licensed practitioner who (1) performs, may be called upon to perform, or who is licensed to perform a comprehensive scope of diagnostic radiologic procedures employing equipment which emits ionizing radiation, and (2) is delegated or exercises responsibility for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, or other procedures which contribute to any significant extent to the site or dosage of ionizing radiation to which a patient is exposed. Radiographers are distinguished from

personnel whose use of diagnostic procedures is limited to a few specific body sites and/or standard procedures, from those personnel in other clinical specialties who may occasionally be called upon to assist in diagnostic radiology, and from those technicians or assistants whose activities do not, to any significant degree, determine the site or dosage of radiation to which a patient is exposed.

Radiologist means a physician certified in radiology by the American Board of Radiology or the American Osteopathic Board of Radiology.

§ 75.3 Applicability.

(a) *Federal Government.* Except as provided in section 983 of the Act, the credentialing standards set out in the Appendixes to this part apply to those individuals who administer or propose to administer radiologic procedures, in each department, agency and instrumentality of the Federal Government as follows:

(1) *Radiographer Standards* apply to all individuals who are radiographers as defined in §75.2 and who are not practitioners excepted by the Act.

(2) *Nuclear Medicine Technologist Standards* apply to all individuals who are nuclear medicine technologists as defined in §75.2, who perform *in vivo* nuclear medicine procedures, and who are not practitioners excepted by the Act. For purposes of this Act, any administration of radiopharmaceuticals to human beings is considered an *in vivo* procedure.

(3) *Radiation Therapy Technologist Standards* apply to all individuals who perform radiation therapy and who are not practitioners excepted by the Act.

(4) *Dental Hygienist Standards* apply to all dental hygienists who perform dental radiography.

(5) *Dental Assistant Standards* apply to all dental assistants who perform dental radiography.

(6) The following persons are deemed to have met the requirements of these standards:

(i) Persons employed by the Federal government as radiologic personnel prior to the effective date of this regulation and who show evidence of current or fully satisfactory performance or certification of such from a licensed practitioner:

(ii) Uniformed military personnel who receive radiologic training from or through the Armed Forces of the United States and who meet standards established by the Department of Defense or components thereof, provided that those standards are determined by such Department or component to offer equivalent protection of patient health and safety:

(iii) Foreign national employed by the Federal government in positions outside of the United States who show evidence of training, experience, and competence determined by the employing agency to be equally protective of patients health and safety; and

(iv) Persons first employed by the Federal government as radiologic personnel after the effective date of this regulation who (*a*) received training from institutions in a State or foreign jurisdiction which did not accredit training in that particular field at the time of graduation, or (*b*) practiced in a State or foreign jurisdiction which did not license that particular field or which did not allow special eligibility to take a licensure examination for those who did not graduate from an accredited educational program; provided that such persons show evidence of training, experience, and competence determined by the Office of Personnel Management or the employing agency to be equally protective of patient health and safety.

(7) The following persons are exempted from these standards:

(i) Persons who are trained to perform, or perform, covered radiologic procedures in emergency situations which preclude use of fully qualified personnel; and

(ii) Students in approved training programs.

(8) A department, agency, or instrumentality of the Federal government may, after consultation with the Secretary, use alternative criteria which it determines would offer equivalent protection of patient health and safety.

(b) *States.* The States may, but are not required to, adopt standards for accreditation and credentialing that are consistent with the standards set out in the appendixes to this part.

APPENDIX A TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIOGRAPHERS

A. Description of the Profession

The radiographer shall perform effectively by:

1. Applying knowledge of the principles of radiation protection for the patient, self, and others.
2. Applying knowledge of anatomy, positioning, and radiographic techniques to accurately demonstrate anatomical structures on a radiograph.
3. Determining exposure factors to achieve optimum radiographic technique with a minimum of radiation exposure to the patient.
4. Examining radiographs for the purpose of evaluating technique, positioning, and other pertinent technical qualities.
5. Exercising discretion and judgment in the performance of medical imaging procedures.
6. Providing patient care essential to radiologic procedures.
7. Recognizing emergency patient conditions and initiating lifesaving first aid.

B. Sponsorship

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the degree or certificate documenting completion of the program.
2. Educational programs may be established in:
(a) Community and junior colleges, senior colleges, and universities;
(b) Hospitals;
(c) Medical schools;
(d) Postsecondary vocational/technical schools and institutions; and
(e) Other acceptable institutions which meet comparable standards.
3. The sponsoring institutions and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and affilitate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

C. Instructional Facilities

1. *General.* Appropriate classroom and clinical space, modern equipment, and supplies for supervised education shall be provided.
2. *Laboratory.* Energized laboratories utilized for teaching purposes shall be certified as required for compliance with Federal and/or State radiation safety regulations. The use of laboratories shall be governed by established educational objectives.
3. *Reference Materials.* Adequate up-to-date scientific books, periodicals, and other reference materials related to the curriculum and profession shall be readily accessible to students.

D. Clinical Education

1. The clinical phase of the educational program shall provide an environment for supervised competency-based clinical education and experience and offer a sufficient and well-balanced variety of radiographic examinations and equipment.
2. An acceptable ratio of students to registered technologists shall be maintained in the clinical teaching environment.
3. A clinical instructor(s), who shall be responsible for supervising students according to objectives, shall be identified for each primary clinical education center.
4. The maximum student enrollment shall not exceed the capacity recommended on the basis of volume and variety of radiographic procedures, resources, and personnel available for teaching purposes.
5. In programs where didactic and clinical experience are not provided in the same institution, accreditation shall be given only to the institution responsible for admissions, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the students in the clinical setting are educational. There shall be a uniform contract between the accredited institution and each of its affiliate hospitals, clearly defining the responsibilities and obligations of each.

E. Curriculum

1. The structure of the curriculum shall be based on not less than two calendar years of full-time study or its equivalent.
2. Instruction shall follow a planned outline that includes:
(a) The assignment of appropriate instructional materials;
(b) Classroom presentations, discussions and demonstrations; and
(c) Examinations in the didactic and clinical aspects of the program.
3. All professional courses, including clinical education, must include specific curriculum content that shall include, but shall not be limited to:
(a) Introduction to radiologic technology;
(b) Medical ethics;
(c) Imaging;
(d) Radiographic processing technique;
(e) Human structure and function;
(f) Medical terminology;
(g) Principals of radiographic exposure;
(h) Radiographic procedures;
(i) Principles of radiation protection;
(j) Radiographic film evaluation;
(k) Methods of patient care;

(l) Pathology;
(m) Radiologic physics; and
(n) Radiation biology.

Related subjects added to the professional curriculum shall meet the requirements of the degree-granting institution.

F. Finances

Financial resources for operation for the educational program shall be assured through regular budgets, gifts, grants, endowments, or fees.

G. Faculty

1. *Program Director.* A program director shall be designated who is credentialed in radiography. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiography shall not be adversely affected by educationally unrelated functions.

(a) *Minimum qualifications.* A minimum of two years of professional experience and proficiency in instructing, curriculum design, program planning, and counseling.

(b) *Responsibilities.* (1) The program director, in consultation with the medical director/advisor (G. 2.) shall be responsible for the organization, administration, periodic review, records, continued development, and general policy and effectiveness of the program.

(2) Opportunities for continuing education shall be provided for all faculty members.

2. *Medical Director/Medical Advisor*—(a) *minimum qualifications.* The medical director/medical advisor shall be a qualified radiologist, certified by the American Board of Radiology, or shall possess suitable equivalent qualifications.

(b) *Responsibilities.* The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for their achievement.

3. *Instructors.* All instructors shall be qualified through academic preparation and experience to teach the assigned subjects.

H. Students

ADMISSION

(a) Candidates for admission shall satisfy the following minimum requirements: Completion of four years of high school; successful completion of a standard equivalency test; or certification of equivalent education by an organization recognized by the United States Department of Education. Courses in physics, chemistry, biology, algebra, and geometry are strongly recommended.

(b) The number of students enrolled in each class shall be commensurate with the most effective learning and teaching practices and should also be consistent with acceptable student-teacher ratios.

I. Records

Records shall be maintained as dictated by good educational practices.

NOTE: Educational programs accredited by an organization recommended by the United States Department of Education are considered to have met these standards.

APPENDIX B TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL HYGIENISTS

A. Sponsorship

Sponsorship must be by an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. The formal training in dental radiography may be a part of a total program of dental hygiene education accredited by an organization recognized by the United States Department of Education.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental hygiene education programs or the State entity responsible for credentialing dental personnel in radiography.

B. Curriculum

Dental radiography training for dental hygienists must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental hygienists to understand the critical nature of the radiological procedures they perform and of the judgments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health,

safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics.* Curriculum content should include: historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology.* Curriculum content should include: Interaction of ionizing radiation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection.* Curriculum content should include: Sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality.* Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques.* Curriculum content should include: imagery geometry; patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extaroral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques.* Curriculum content should include: solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting.* Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that Dental Hygienists have the opportunity to develop competence in making radiographs. Faculty supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice where there is not direct supervision by faculty.

—Dental hygienists must demonstrate knowledge of radiation safety measures before making radiographs and, where possible, should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs and radiographic surveys including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

C. Student Evaluation

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

D. Faculty

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity which approved the training program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

E. Facilities

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment must be available and of a quality that assures that films will not be damaged or lost.

F. Learning Resources

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized

reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards. Under existing licensure provisions in all States, becoming a dental hygienist requires graduation from a dental hygiene education program accredited by an organization recognized by the United States Department of Education. In lieu of this requirement, Alabama accepts graduation from a State-approved preceptorship program.

APPENDIX C TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL ASSISTANTS

A. Sponsorship

Sponsorship must be an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: Defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. Dental radiography training may be freestanding (as a continuing education course offered by State dental/dental auxiliary societies, or by dental/dental auxiliary education programs); or be a part of an educational program in dental assisting. Such dental assisting education programs may be accredited by an organization recognized by the United States Department of Education; or located in a school accredited by an institutional accrediting agency recognized by the the United States Department of Education or approved by the State agency responsible for secondary and postsecondary education, or approved by a Federal agency conducting dental assistant education in that Agency.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental assisting education programs, or the State entity responsible for credentialing dental personnel in radiography.

B. Curriculum

Dental radiography training for dental assistants must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental assistants to understand the critical nature of the radiological procedures they perform and of the judgments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health, safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics.* Curriculum content should include: Historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology.* Curriculum content should include: interaction of ionizing radiation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection.* Curriculum content should include: sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality.* Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques.* Curriculum content should include: imagery geometry; patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extraoral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques.* Curriculum content should include: Solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting.* Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that Dental Assistants have the opportunity to develop competence in making radiographs. The clinical experience may be conducted in the dental office in which the Dental Assistant is employed or is serving an externship. Faculty and/or employing dentist supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice when there is not direct supervision by faculty and/or the employing dentist.

—Dental Assistants must demonstrate knowledge of radiation safety measures before making radiographs, and where possible should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs and radiographic surveys, including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

C. Student Evaluation

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

D. Faculty

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity (or Federal agency where appropriate) which approves the educational program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

E. Facilities

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment must be available and of a quality that assures that films will not be damaged or lost.

F. Learning Resources

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX D TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR NUCLEAR MEDICINE TECHNOLOGISTS

A. Sponsorship

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the degree or certificate documenting completion of the program.

2. Educational programs may be established in:

(a) Community and junior colleges, senior colleges, and universities;

(b) Hospitals and clinics;

(c) Laboratories;

(d) Medical schools;

(e) Postsecondary vocational/technical schools and institutions; and

(f) Other acceptable institutions which meet comparable standards.

3. The sponsoring institution and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and

affiliate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

4. Responsibilities of the sponsor and each affiliate for program administration, instruction, supervision, etc., must be carefully described in written affiliation agreements.

B. Curriculum

Instruction must follow a plan which documents:

1. A structured curriculum including clinical education with clearly written syllabi which describe learning objectives and competencies to be achieved. The curriculum shall be based on not less than one calendar year of full-time study or its equivalent.

2. The minimum professional curriculum that includes the following:

(a) Methods of patient care;

(b) Radiation safety and protection;

(c) Nuclear medicine physics;

(d) Radiation physics;

(e) Nuclear instrumentation;

(f) Statistics;

(g) Radionuclide chemistry;

(h) Radiopharmacology;

(i) Departmental organization and function;

(j) Radiation biology;

(k) Nuclear medicine *in vivo* and *in vitro* procedures;

(l) Radionuclide therapy;

(m) Computer applications; and

(n) Clinical practicum.

3. Assignment of appropriate instructional materials.

4. Classroom presentations, discussions, and demonstrations.

5. Supervised practice, experience, and discussions. This shall include the following:

(a) Patient care and patient recordkeeping;

(b) Participation in the quality assurance program;

(c) The preparation, calculation, identification, administration, and disposal of radiopharmaceuticals;

(d) Radiation safety techniques that will minimize radiation exposure to the patient, public, fellow workers, and self;

(e) The performance of an adequate number and variety of imaging and non-imaging procedures; and

(f) Clinical correlation of nuclear medicine procedures.

6. Evaluation of student's knowledge, problem-solving skills, and motor and clinical competencies.

7. The competencies necessary for graduation.

C. Resources

1. The program must have qualified program officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. The following program officials must be identified:

(a) *Program Director*—(1) *Responsibilities.* The program director of the educational program shall have overall responsibility for the organization, administration, periodic review, continued development, and general effectiveness of the program. The director shall provide supervision and coordination to the instructional staff in the academic and clinical phases of the program. Regular visits to the affiliates by the program director must be scheduled.

(2) *Qualifications.* The program director must be a physician or nuclear medicine technologist. The program director must demonstrate proficiency in instruction, curriculum design, program planning, and counseling.

(b) *Medical Director*— (1) *Responsibilities.* The medical director of the program shall provide competent medical direction and shall participate in the clinical instruction. In multiaffiliate programs each clinical affiliate must have a medical director.

(2) *Qualifications.* The medical director must be a physician qualified in the use of radionuclides and a diplomate of the American Board(s) of Nuclear Medicine, or Pathology, or Radiology, or possess suitable equivalent qualifications.

(c) *Clinical Supervisor.* Each clinical affiliate must appoint a clinical supervisor.

(1) *Responsibilities.* The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical affiliate.

(2) *Qualifications.* The clinical supervisor must be a technologist credentialed in nuclear medicine technology.

2. *Instructional Staff*—(a) *Responsibilities.* The instructional staff shall be responsible for instruction in the didactic and/or clinical phases of the program. They shall submit course outlines for each course assigned by the program director; evaluate students and report progress as required by the sponsoring institution; and cooperate with the program director in the periodic review and upgrading of course material.

(b) *Qualifications.* The instructors must be qualified, knowledgeable, and effective in teaching the subjects assigned.

(c) *Instructor-to-student ratio.* The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional development.* Accredited programs shall assure continuing education in the health profession or occupation and ongoing instruction for the faculty in curriculum design and teaching techniques.

3. Financial resoures for continued operation of the educational program must be assured.

4. *Physical Resources.* (a) *General.* Adequate classrooms, laboratories, and other facilities shall be provided.

(b) *Equipment and Supplies.* Modern nuclear medicine equipment, accurately calibrated, in working order, and meeting applicable Federal and State standards, if any, must be available for the full range of diagnostic and therapeutic procedures as outlined in the curriculum.

(c) *Reference Materials.* Reference materials appropriate to the curriculum shall be readily accessible to students.

(d) *Records.* Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources.* Instructional aids such as clinical materials, reference materials, demonstration and other multimedia materials must be provided.

D. Students

ADMISSION REQUIREMENTS

Persons admitted into nuclear medicine technology programs shall have completed high school or its equivalent. They shall have completed postsecondary courses in the following areas:

(1) Human anatomy and physiology;
(2) Physics;
(3) Mathematics;
(4) Medical terminology;
(5) Oral and written communications;
(6) General chemistry; and
(7) Medical ethics.

Prerequisites may be completed during nuclear medicine training. Educational institutions such as junior colleges, universities, and technical vocational institutes may provide these prerequisite courses as part of an integrated program in nuclear medicine technology (i.e., two to four years).

E. Operational Policies

Students may not take the responsibility nor the place of qualified staff. However, students may be permitted to perform procedures after demonstrating proficiency, with careful supervision.

F. Continuing Program Evaluation

1. Periodic and systematic review of the program's effectiveness must be documented.

2. One element of program evaluation shall be the initial employment of graduates of the program.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX E TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIATION THERAPY TECHNOLOGISTS

A. Sponsorship

1. Educational programs may be established in:

(a) Community and junior colleges, senior colleges, and universities;

(b) Hospitals, clinics, or autonomous radiation oncology centers meeting the criteria for major cancer management centers or meeting demonstrably equivalent standards;

(c) Medical schools; and

(d) Postsecondary vocational/technical schools and institutions.

2. The sponsoring institution and affiliates, if any, must be accredited by recognized agencies or meet equivalent standards. When more than one clinical education center is used, each must meet the standards of a major cancer management center.

3. When didactic preparation and supervised clinical education are not provided in the same institution, accreditation must be obtained by the sponsoring institution for the total program. This institution will be the one responsible for admission, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the student in the clinical setting are educational. There shall be a uniform, written, affiliation agreement between the accredited institution and each clinical education center, clearly defining the responsibilities and obligations of each.

B. Curriculum

Educational programs of 24 months and 12 months or their equivalents may be developed. A 24-month program shall admit those candidates with a high school diploma (or equivalent) as outlined in D.1. The 12-month program shall be designed for those students admitted with backgrounds as outlined in D.2.

Instruction must follow a plan which documents:

1. A structured curriculum with clearly written course syllabi which describe competencies and learning objectives to be achieved. The curriculum shall include but not necessarily be limited to the following:

(a) Orientation to radiation therapy technology;
(b) Medical ethics and law;
(c) Methods of patient care;
(d) Medical terminology;
(e) Human structure and function;
(f) Oncologic pathology;
(g) Radiation oncology;
(h) Radiobiology;
(i) Mathematics;
(j) Radiation physics;

(k) Radiation protection;

(l) Radiation oncology technique;

(m) Radiographic imaging; and

(n) Clinical dosimetry.

The curriculum must include a plan for well-structured competency-based clinical education.

2. Assignment of appropriate instructional materials.

3. Classroom presentations, discussions, and demonstrations.

4. Supervised clinical education and laboratory practicum.

5. Evaluation of students to assess knowledge, problem-solving skills, and motor and clinical competencies.

6. Program graduates must demonstrate competencies including, but not limited to, the following:

(a) Practice oral and written communications;

(b) Maintain records of treatment administered;

(c) Perform basic mathematical functions;

(d) Demonstrate knowledge of human structure, function, and pathology;

(e) Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;

(f) Provide basic patient care and cardiopulmonary resuscitation;

(g) Deliver a planned course of radiation therapy;

(h) Verify physician's prescribed course of radiation therapy and recognize errors in computation;

(i) Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;

(j) Produces and utilize immobilization and beam directional devices;

(k) Prepare commonly used brachytherapy sources;

(l) Demonstrate knowledge of methods of calibration of equipment, and quality assurance;

(m) Prepare isodose summations;

(n) Detect malfunctioning equipment;

(o) Apply rules and regulations for radiation safety, and detect defects which might pose a radiation hazard;

(p) Understand the function of equipment and accessories;

(q) Demonstrate knowledge of methods of continuing patient evaluation (follow up);

(r) Apply wedge and compensating filters;

(s) Recognize patients' clinical progress, complications, and demonstrate knowledge of when to withhold treatment until consultation with the physician; and

(t) Interact with patients and families concerning the physical and psychological needs of patients.

C. Resources

1. *Program Officials.* The program must have a qualified program official or officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. A program director is necessary; other program officials may be required.

(a) *Program Director*—(1) *Responsibilities.*

—The director of the educational program shall be responsible for the organization, administration, periodic review, continued development, and general effectiveness of the program. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiation therapy technology shall not be adversely affected by educationally unrelated functions.

—In a college-sponsored program, or a hospital-sponsored multiple affiliate program, the program director shall be a employee of the sponsoring institution. A schedule of regular affiliate visits must be maintained.

(2) *Qualifications.*

—Must be a technologist qualified in radiation therapy technology and educational methodologies.

—Must be credentialed in radiation therapy technology or possess suitable equivalent qualifications.

—Must have at least two years' experience as an instructor in an accredited educational program.

(b) *Clinical Supervisor.* Each clinical education center shall appoint a clinical supervisor.

(1) *Responsibilities.* The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical education center.

(2) *Qualifications.* Must be a technologist, with suitable experience, qualified in radiation therapy technology and educational methodologies and must be credentialed in radiation therapy technology.

(c) *Medical Director/Medical Advisor*—

(1) *Responsibilities.* The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for achievement.

(2) *Qualifications.* The medical director/medical advisor shall be a qualified radiation oncologist certified by the American Board of Radiology, or shall possess suitable equivalent qualifications.

2. *Instructional Staff*— (a) *Responsibilities.* The instructional staff shall be responsible for submitting course outlines for each course assigned by the program director; evaluating students and reporting progress as required by the sponsoring institution; and cooperating with the program director

in the periodic review and upgrading of course material.

(b) *Qualifications.* The instructors must be individually qualified, must be effective in teaching the subjects assigned, and must meet the standards required by the sponsoring institution.

(c) *Instructor-to-Student Ratio.* The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional Development.* Programs shall have a policy that encourages continuing education in radiation therapy technology and assures ongoing instruction for the faculty in curriculm design and teaching strategies.

3. *Financial Resources.* Financial resources for continued operation of the educational program must be assured.

4. *Physical Resources*—(a) *General.* Adequate classrooms, laboratories, and other facilities shall be provided. All affiliated institutions shall provide space required for these facilities.

(b) *Equipment and Supplies.* Appropriate modern equipment and supplies in sufficient quantities shall be provided.

(c) *Laboratory.* Energized laboratories must meet Federal and/or State radiation and safety regulations.

(d) *Reference Materials.* An adequate supply of up-to-date books, periodicals, and other reference materials related to the curriculum and the profession shall be readily available to students.

(e) *Records.* Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources.* Instructional aids such as clinical materials, reference materials, and demonstration and other multimedia materials must be provided.

D. Students

ADMISSION

1. Applicants must be high school graduates (or equivalent) with an educational background in basic science and mathematics.

2. For admission to a 12-month program, the candidate must satisfy one of the following requirements:

(a) Graduation from an accredited or equivalent program in radiography.

(b) Successful completion or challenge of courses in the following prerequisite content areas:

—Radiation physics;
—Human structure and function;
—Radiation protection;
—Medical ethics and law;
—Methods of patient care;
—Medical terminology; and
—Mathematics.

(c) Successful demonstration of the following competencies:

—Practice oral and written communications;
—Perform basic mathematical functions;
—Demonstrate knowledge of human structure and function;
—Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;
—Provide basic patient care and cardiopulmonary resuscitation;
—Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;
—Apply rules and regulations for radiation safety, detect defects which might pose a radiation hazard, and maintain control, if a radiation accident occurs; and
—Interact with patients and families concerning patients physical and psychological needs.

E. Continuing Program Evaluation

1. A process for periodic and systematic review of the program's effectiveness must be documented and reflected in policies.

2. Program evaluation shall include the employment performance of recent graduates.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX F TO PART 75—STANDARDS FOR LICENSING RADIOGRAPHERS, NUCLEAR MEDICINE TECHNOLOGISTS, AND RADIATION THERAPY TECHNOLOGISTS

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

A. Licensure

1. Only eligible applicants who have passed the licensure examination shall be licensed as Radiographers, Nuclear Medicine Technologists, or Radiation Therapy Technologists.

2. Licenses shall be renewed at periodic intervals.

B. Eligibility

1. For regular eligibility to take the licensure examination, applicants shall have successfully completed an accredited program of formal education in radiography, nuclear medicine technology, or radiation therapy technology.

2. Special eligibility to take the licensure examination shall be provided for applicants whose training and/or experience are equal

to, or in excess of, those of a graduate of an accredited educational program.

C. Examination

A criterion-referenced examination in radiography, nuclear medicine technology, or radiation therapy technology shall be utilized to test the knowledge and competencies of applicants.

D. Continuing Competency

The licensed Radiographer, Nuclear Medicine Technologist, or Radiation Therapy Technologist shall maintain continuing competency in the area in which he/she is practicing.

E. Policies and Procedures

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, objectivity, and fairness in the certifying process. The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organization to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.

APPENDIX G TO PART 75—STANDARDS FOR LICENSING DENTAL HYGIENISTS AND DENTAL ASSISTANTS IN DENTAL RADIOGRAPHY

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

Currently, Dental Hygienists are credentialed through individual State licensure processes, all of which include assessment of competence in dental radiography. In all States, Dental Hygienists are required to be licensed prior to practicing. The existing State dental hygiene licensure processes meet the intent and purpose of the Consumer-Patient Radiation Health and Safety Act of 1981 and the standards for licensing Dental Hygienists in dental radiography set forth below.

A. Licensure/Permit

1. To those who have passed a licensure or designated dental radiography examination, a license or permit shall be issued by the State entity responsible for credentialing dental personnel.

2. Licenses or permits shall be renewed at periodic intervals.

B. Eligibility

1. An individual shall provide proof of graduating student status or graduation from an accredited or approved dental hygiene or dental assisting education program.

2. For dental assistants, special eligibility to take the examination shall be provided to applicants with appropriate combinations of training and/or experience.

C. Examination

A criterion-referenced examination in dental radiography shall be utilized to test the knowledge and competencies of applicants.

D. Continuing Competency

The Dental Hygienist or Dental Assistant shall be required to maintain continuing competency in the area in which he/she is practicing.

E. Policies and Procedures

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, objectivity, and fairness in the certifying process. The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organization to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.